Supreme Court, U.S.
FILED
981424 MAR 8 - 1999
OFFICE OF THE CLERK

No. _____

In The

Supreme Court of the United States

October Term, 1998

COLLAGEN CORPORATION,

Petitioner,

v.

CHARLOTTE KENNEDY and ROBERT KENNEDY,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

FREDERICK DOUGLAS BAKER
Counsel of Record
KATHLEEN D. PATTERSON
SEDGWICK, DETERT, MORAN & ARNOLD
One Embarcadero Center, 16th Floor
San Francisco, California, 94111-3628
Telephone: (415) 781-7900

Counsel for Petitioner

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

10088

QUESTIONS PRESENTED

The plaintiff in a diversity products liability action hired a doctor to testify, as an expert, that her condition was caused by an FDA-approved medical device prescribed by her physician and produced by the defendant. The doctor conceded that (1) there was no consensus in the relevant medical community that the device causes the condition, (2) there is nothing in the medical literature which associates the device with the condition, and (3) he has conducted no research on the question whether the device causes the condition. Nonetheless, the doctor looked at various bits of data, conducted his own process of "analogical reasoning," and concluded the device "may have" caused the condition. This, the court of appeals ruled, was sufficient to get to a jury. The questions presented are:

(i) Where the medical opinion of a proffered expert finds no support in either the medical community or the medical literature, and does not derive from the witness' own research, does Rule 702 of the Federal Rules of Evidence require the proponent of the expert to establish, by a preponderance of the evidence based upon independent validation, that the expert's methodology is scientifically reliable?

(ii) Does *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) establish, as the court of appeals suggests, a standard of certainty for an expert scientific opinion that supersedes state law standards?

RULE 29.6 STATEMENT

Petitioner Collagen Corporation has no parent corporation and no non-wholly owned subsidiaries.

LISTING OF PARTIES TO THE PROCEEDING

The caption to this case contains the names of all parties. In August 1998 Collagen Corporation changed its name to Collagen Aesthetics, Inc.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
RULE 29.6 STATEMENT	ii
LISTING OF PARTIES TO THE PROCEEDING	ii
OPINIONS BELOW	1
JURISDICTION	1
STATUTE INVOLVED	2
RELATED ISSUES	2
STATEMENT OF THE CASE	2
A. INTRODUCTION	2
B. THE LAWSUIT	3
C. COLLAGEN'S FIRST SUMMARY JUDGMENT MOTION	4
D. REMAND TO THE DISTRICT COURT	8
E. RENEWED SUMMARY JUDGMENT MOTION	10
F. THE COURT OF APPEALS' DECISION	14
1. Scientific Knowledge	14
2. Assisting the Trier of Fact	17
REASONS FOR GRANTING THE PETITION	19
A. THE ADMISSIBILITY OF AN UNVALIDATED BOOTSTRAP OPINION IS AN IMPORTANT AND RECURRING ISSUE – UPON WHICH THE LOWER COURTS DISAGREE – LEFT UNRESOLVED BY *DAUBERT* AND *JOINER*	19

TABLE OF CONTENTS – Continued

Page

B. THERE IS CONFLICT ON THE QUESTION OF WHICH PARTY HAS THE BURDEN OF PROVING THAT AN EXPERT'S TESTIMONY IS BASED ON SCIENTIFICALLY RELIABLE METHODOLOGY 26

C. THE COURT OF APPEALS WRONGLY HELD THAT *DAUBERT* ESTABLISHES A STANDARD OF CERTAINTY FOR EXPERT OPINIONS THAT SUPERSEDES SUBSTANTIVE STATE LAW 27

CONCLUSION 30

TABLE OF AUTHORITIES

Page

Federal Cases

Ambrosini v. Labarraque, 101 F.3d 129 (D.C. Cir. 1996), *cert. dismissed, Upjohn v. Ambrosini*, ___ U.S. ___, 117 S.Ct. 1572 (1997) 23, 25

Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378 (4th Cir. 1995) 25

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995) ..... *passim*

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) ..... *passim*

Dukes v. Illinois Central R. Co., 934 F.Supp. 939 (N.D. Ill. 1996) 27

General Electric v. Joiner, ___ U.S. ___, 118 S.Ct. 512 (1997) 20

Grimes v. Hoffman-LaRoche, Inc., 907 F.Supp. 33 (D. N.H. 1995) 27

Hall v. Baxter Healthcare Corp., 947 F.Supp. 1387 (D. Ore. 1996) 28

Hardt v. Heidweyer, 152 U.S. 547 (1894) 9

In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717 (3d Cir. 1994), *cert. denied*, 523 U.S. 1190 (1995) 24

McCullock v. H.B. Fuller Co., 61 F.3d 1078 (2d Cir. 1995) 24

Mitchell v. Gencorp Inc., ___ F.3d ___, 1999 WL 5105 (10th Cir. 1999) 24

TABLE OF AUTHORITIES – Continued

Page

Moore v. Ashland Chemical, Inc., 151 F.3d 269 (5th Cir. 1998) 24

Muzzey v. Kerr-McGee Chemical Corp., 921 F.Supp. 508 (N.D. Ill. 1996) 27

Poust v. Huntleigh Healthcare, 998 F.Supp. 478 (D. N.J. 1998) 26, 27

Sanderson v. IFF, 950 F.Supp. 981 (C.D. Cal. 1996) 26

Schmaltz v. Norfolk & Western Railway Co., 878 F.Supp. 1119 (N.D. Ill. 1995) 27

TRW Title Insurance Co. v. Security Union Title Ins. Co., 890 F.Supp. 756 (N.D. Ill. 1995)..... 27

Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349 (6th Cir. 1992)..... 22

United States v. Scheffer, ___ U.S. ___, 118 S.Ct. 1261 (1998) 19

White v. Chicago Pneumatic Tool Co., 994 F.Supp. 1478 (S.D. Ga. 1988) 27

Zuchowitz v. United States, 140 F.3d 38 (2d Cir. 1998)..... 24

STATE CASES

Bromme v. Pavitt, 5 Cal.App.4th 1487 (1992) 28

Cottle v. Superior Court, 3 Cal.App.4th 1367 (1992) 28

Dumas v. Cooney, 235 Cal.App.3d 1573 (1991)..... 28

TABLE OF AUTHORITIES – Continued

Page

Jones v. Ortho Pharmaceutical Corp., 163 Cal.App.3d 396 (1985) 4, 6, 17, 27, 28

Memorial Chapel v. Dudler, 231 Cal.App.3d 190 (1991) 28

Ochoa v. Pacific Gas & Electric Co., 61 Cal.App.4th 1480 (1998) 28

People v. Benson, 52 Cal.3d 754 (1990) 10

Zipton v. Workers' Comp. Appeals Board, 218 Cal.App.3d 980 (1990) 28

FEDERAL STATUTES

28 U.S.C § 1254(1) 1

Federal Rule of Evidence 702 ..... *passim*

PETITION FOR WRIT OF CERTIORARI

Collagen Corporation ("Collagen") hereby petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals is reported at 161 F.3d 1226. (App., *infra*, pp. 1-13.) The opinion of the district court is reported at 991 F.Supp. 1185. (App., *infra*, pp. 14-21.)

The opinion of the court of appeals in a prior appeal is reported at 67 F.3d 1453. (App., *infra*, pp. 24-42.) The order of the district court is not reported. (App., *infra*, pp. 43-44.) The unpublished opinions of the court of appeals in an earlier prior appeal are cited at 967 F.2d 587 and 974 F.2d 1342. (App., *infra*, pp. 45-54, 55-56.) The earlier order of the district court preceding that appeal is unreported. (App., *infra*, pp. 57-62.)

JURISDICTION

The judgment of the court of appeals was filed December 7, 1998. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTE INVOLVED

Rule 702 of the Federal Rules of Evidence provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

RELATED ISSUES PENDING BEFORE THE COURT

The issues raised herein are related, but not identical, to the issues presented in the recently-argued *Kumho Tire Company, Ltd. v. Carmichael*, No. 97-1709.

STATEMENT OF THE CASE

A. INTRODUCTION

This Court has said unequivocally that district court judges are charged with the responsibility of ensuring that expert medical and scientific opinions – before they are heard by juries – are demonstrated to have been derived by a methodology that scientists in the field consider reliable.

It commonly occurs that the proponent of an expert attempts to bootstrap "scientific reliability" through the testimony of the very expert whose methodology is under scrutiny. Some published decisions of the circuit courts of appeals sensibly hold that where this is the case, the

proponent must provide independent validation of the reliability of the expert's analysis.

Other published circuit court decisions hold that an expert's self-validation does not offend *Daubert*. The Ninth Circuit here not only aligns itself with these cases, but goes one step farther: It endorses the methodology of an expert who does not even claim to have used "traditional" methodology. It approves the idiosyncratic beliefs of a doctor in the acknowledged absence of anything in the medical and scientific literature which confirms those beliefs, and in the acknowledged absence of any consensus among other physicians in the field – neither a majority nor an "acknowledged minority" – that the doctor's beliefs are derived from a scientifically reliable methodology or are in fact correct.

The court of appeals' decision strips *Daubert* of meaning. The gatekeeper has lost his gate. The disagreement which divides the court of appeals should be resolved in favor of those courts that enforce the policy concerns advanced by *Daubert*, and against those courts that have eviscerated the *Daubert* principles.

B. THE LAWSUIT

Charlotte Kennedy filed a lawsuit claiming she suffers from "atypical" systemic erythematosus ("SLE")[1]

---

[1] Kennedy's opinion witness, Dr. Spindler, describes her condition as "atypical" SLE because true SLE, according to the American College of Rheumatology, requires a finding of at least four signs or symptoms from a list of many, and Kennedy only has two. This same "expert" admits that neither the

caused by her use of Zyderm, an FDA-approved medical device made by Collagen. Zyderm, used by physicians to treat skin defects, is derived from animal collagen.

Under California law, which governs this diversity action, Kennedy cannot recover unless she can meet her burden of proof on causation: She must prove, to a reasonable degree of medical probability based upon competent expert testimony, that Zyderm ***more likely than not*** caused her "atypical" SLE. *Jones v. Ortho Pharmaceutical Corp.*, 163 Cal.App.3d 396, 403 (1985).

As trial approached, following fifteen months of extensive discovery, Kennedy submitted her disclosure of expert witnesses. Collagen deposed each; none would testify that Zyderm caused Kennedy's disease. Her treating rheumatologist, identified as an expert on causation, said he had "no idea" whether Zyderm played a role. Another such expert said only that a causative role was "possible." The others offered similar testimony.

C. COLLAGEN'S FIRST SUMMARY JUDGMENT MOTION

Collagen moved for summary judgment on the ground that Kennedy's experts' testimony could not sustain her burden of proof. At the hearing on the motion

---

American College of Rheumatology nor anyone else has recognized criteria for "atypical" SLE.

Kennedy's lawyers – sensing impending defeat – produced an affidavit signed by a Dr. Joseph Spindler. Spindler had never been disclosed as an expert (the deadline for disclosure had long since passed), and Collagen had never seen the affidavit, much less had an opportunity to depose Spindler.

The first substantive paragraph of Spindler's affidavit says that (1) Kennedy's pre-Zyderm medical records do not indicate that she had SLE, (2) her post-Zyderm records show an SLE diagnosis and "anti-histone antibody," and (3) the "existence of anti-histone antibody is ***suspect*** [sic] that her immune system was triggered by an external source, which ***could have been*** Zyderm."

The next paragraph states that (1) Kennedy's "medical history, records and current laboratory results are ***consistent with a temporal relationship***" between Zyderm and SLE, and (2) laboratory results "reveal a change in her ANA [antinuclear antibodies]" and "the existence of anticentromere antibody."

The third and last paragraph says, "[b]ased on reasonable medical probability," that Kennedy had an immunologic reaction to Zyderm which was a "substantial factor" in causing a "changing immunological picture." The only stated basis for this conclusion was "the temporal relationship."

Thus, Spindler's causation opinion had two bases: (1) the presence of "antihistone antibody" and "anticentromere antibody," and a "change" in "ANA";[2] and (2)

---

[2] These antibodies, and changes in antibodies, occur in all patients who suffer from SLE. To say that Zyderm causes SLE

that Kennedy became ill at some time after receiving Zyderm. The district court granted summary judgment. (App., *infra*, pp. 57-62.) The court considered Spindler's affidavit and said:

> [The] affidavit does not sustain plaintiff's burden of establishing a genuine issue of material fact on causation. His opinion is based primarily on the temporal relationship between plaintiff's use of [Zyderm] and the development of her disease (*post hoc, ergo propter hoc*). The most that he can say is that [Zyderm] injections were "suspect," and that her condition "could have been" caused by taking [Zyderm]. There do not appear to be any other laboratory tests of plaintiff, epidemiological evidence, or toxicological evidence upon which the opinion is based.

(App., *infra*, p. 61.)

On June 8, 1992, the court of appeals (Reinhardt, Ferguson, and Kozinski) affirmed in a per curiam memorandum opinion without dissent. (App., *infra*, pp. 55-56.) The court, noting that under California law "Kennedy was required to prove causation 'within a reasonable medical probability,' *Jones v. Ortho Pharmaceutical Corp.*, 163 Cal.App.3d 396, 402 (1985)," said:

> [Kennedy's] expert affidavits on causation, however, were either speculative, highly equivocal,

---

because Kennedy was exposed to Collagen, developed SLE, and tested positive for antibodies is akin to saying that aspirin causes AIDS because a patient consumed aspirin, developed AIDS, and tested positive for HIV.

> or both. They thus provided an insufficient basis for a reasonable jury to find causation.

(App., *infra*, p. 56.)

The court granted a petition for rehearing, withdrew its earlier decision, and on June 8, 1992 entered a new memorandum decision reversing the district court. (App., *infra*, pp. 45-54.) The court said:

> Dr. Spindler affirmed that "[b]ased on reasonable medical probability," the Zyderm injections caused Charlotte Kennedy's systemic immunological injuries. Dr. Spindler based his opinion on his examination of Kennedy; review of her medical history and records; numerous laboratory tests of Kennedy which showed a positive ANA, anti-histone antibody, and anti-centromere antibody; and the temporal relationship between the injections and her condition. Accepted on its own terms, the affidavit demonstrated a "reasonable medical probability" that the defendant's conduct caused Kennedy's injuries.

(App., *infra*, pp. 47-48.) That Spindler's opinion was couched in terms of suspicions and "could have beens" was said to be of no moment; the affidavit "read in its entirety, clearly stated his opinion of reasonable medical probability." Thus, "[a] jury was entitled to hear Dr. Spindler's testimony." (App., *infra*, p. 49.)

In dissent, Circuit Judge Kozinski found it important that Spindler's opinion was based on suspicion, speculation, and *post hoc, ergo propter hoc* reasoning, and observed:

> Dr. Spindler also adds that "[m]ore recently, I have obtained and evaluated current laboratory

> test results for her, which reveal a change in her ANA, and in the existence of anticentromere antibody, previously not present." *Id.* Nowhere does Dr. Spindler explain the meaning of "ANA" or "anticentromere antibody," nor does he intimate what either of these has to do with plaintiff's case against the defendant.
>
> ***Dr. Spindler's affidavit is*** simply too indefinite to establish a "reasonable medical probability" that Kennedy's disorder is in any way linked with defendant's collagen treatments; it is ***rank speculation***.

(App., *infra*, p. 54 (emphasis supplied).)

D. REMAND TO THE DISTRICT COURT

After remand to the district court, two significant events occurred. First, this Court decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) (*"Daubert I"*) and the Ninth Circuit, on remand, decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995) *cert. denied*, 516 U.S. 869 (1995) (*"Daubert II"*). Second, Collagen deposed Spindler.

When Spindler was asked repeatedly and directly whether he could testify to a reasonable degree of medical probability that Kennedy's "atypical" SLE was ***more likely than not*** caused by Zyderm, Spindler offered this response:

> I can say it ***may be*** caused by – but with any degree beyond that, I cannot. [Emphasis supplied.]

Pressed for the basis of his speculation that Zyderm ***"may"*** have been the cause, Spindler conceded these facts:

- There is no consensus among rheumatologists that Zyderm causes SLE, "atypical" or otherwise.
- Neither he nor anyone else in the medical and scientific community has conducted an epidemiological study to determine whether Zyderm causes SLE or "atypical" SLE.
- There is no study in the peer-reviewed literature which reports that Zyderm causes SLE or "atypical" SLE.
- There is no animal study which demonstrates that Zyderm causes SLE or "atypical" SLE.
- No textbook to which he referred, or upon which he relied, says that Zyderm causes SLE or "atypical" SLE.
- He had never examined another patient who used Zyderm and developed SLE or "atypical" SLE.

At bottom, Spindler's causation opinion rested on a temporal relationship – Kennedy used Zyderm, then she developed "atypical" SLE. Asked point blank for the basis of his opinion that Zyderm "***may***" have caused Kennedy's condition, Spindler said:

> A. There appears to be a temporal association in the time she received her bovine collagen implant and the onset of her condition.
>
> Q. Do you have ***any other basis*** for that opinion other than the temporal relationship?
>
> A. ***No sir***. [Emphasis supplied.][3]

---

[3] Both this Court and California courts have rejected the notion that an inference of causation can be drawn from *post hoc, ergo propter hoc* reasoning. *See Hardt v. Heidweyer*, 152 U.S. 547,

E. RENEWED SUMMARY JUDGMENT MOTION

Armed with Spindler's deposition testimony which purported to explain the basis for the speculative conclusions expressed in his affidavit, Collagen again moved for summary judgment. The motion demonstrated that Spindler's testimony was inadmissible because: (1) the conclusions were not "scientific knowledge" derived by the "scientific method" as required by *Daubert I* and *Daubert II* and (2) the causation opinion failed to meet California's burden of proof because Spindler could not or would not testify that Zyderm was, ***more likely than not***, the cause of Kennedy's "atypical" SLE.

Kennedy's opposition brief ***did not provide any independent, objective validation that Spindler's "methodology" was based on scientifically valid principles***. Indeed, it did not even establish that Spindler – a clinician – is an expert in determining the cause of diseases such as SLE or "atypical" SLE; expertise in diagnosis and treatment, even assuming Spindler has such expertise, does not mean Spindler is an expert in establishing causation.

Kennedy's brief merely attempted to provide some cover for Spindler's bootstrap opinion – the opinion that Judge Kozinski described as "rank speculation." (App., *infra*, p. 54.) Kennedy pointed to passages in Spindler's deposition testimony where he said that:

---

558 (1894) ("*Post hoc, propter hoc* is not, however, sufficient, and the rule of causation implies some other sequence than that of time"); *People v. Benson*, 52 Cal.3d 754, 781 (1990) ("temporal priority does not establish causal force: it is a logical fallacy to reason *post hoc, ergo propter hoc*").

1. He examined Kennedy and reviewed her medical history and records.

   But Spindler conceded this only established a temporal relationship – that Kennedy developed "atypical" SLE after being treated with Zyderm.

2. He relied upon an article he wrote in the Annals of Internal Medicine.

   But Spindler conceded that this article said nothing whatever about SLE or "atypical" SLE, the disease in issue here, and conceded that nowhere in the published literature had anyone associated Zyderm with SLE or "atypical" SLE.

3. He proposed an "analogical theory" which goes like this: (1) There is a phenomenon known as "drug-induced" lupus, in which exposure to a drug causes temporary lupus-like symptoms; (2) he believes Zyderm "triggers" the immune system, causing the production of antibodies; (3) the presence of antibodies is consistent with SLE or "atypical" SLE; (4) Kennedy was treated with Zyderm; (5) Kennedy tested positive for antibodies; (6) therefore, based upon the "drug-induced" lupus model, Zyderm may have caused Kennedy's "atypical" SLE.

   But Spindler conceded that (1) no text he considers authoritative associates Zyderm with "drug-induced" lupus; (2) nowhere in the medical and scientific literature is it suggested that Zyderm is associated with "drug-induced" lupus, SLE, or "atypical" SLE; (3) Kennedy does not suffer from "drug-induced" lupus; (4) "drug-induced" lupus

merely describes a temporal relationship; (5) antibodies are produced in response to all foreign bodies; and (6) all patients with autoimmune disease test positive for antibodies – it is a symptom of the disease – and many healthy patients test positive for antibodies in the absence of any autoimmune disease.

4. He relied upon a report of the Texas Department of Health which purportedly showed other incidences of persons who had been treated with collagen and at some point developed autoimmune disease.

   But Spindler concedes that both the FDA and the Texas Department of Health, after investigations prompted by agitation from plaintiffs' lawyers, continue to approve the use of Zyderm. Moreover, (1) the Texas report was a draft report that was never made final, (2) the draft report concerned two conditions – dermatomyositis and polymyositis – that Spindler concedes Kennedy does not have, and (3) after the draft report, the FDA entirely re-reviewed Collagen's Zyderm application and confirmed that its decision to approve the device was appropriate.

All of this – Spindler's concession of the lack of either medical consensus or support in the medical/scientific literature for his views, as well as his "analogical" causation hypothesis – was before the district court when ~~it~~ addressed Collagen's summary judgment motion. The court reviewed Spindler's affidavit, the reasons for his conclusions as described above, and the standards established by *Daubert I* and *Daubert II*.

The district court then granted Collagen's summary judgment motion. (App., *infra*, pp. 14-21.) The court noted that one of the principal methods by which the proponent of expert scientific testimony can demonstrate the reliability of the expert's methods is by showing that his research has been published in a peer-reviewed journal. The one article Kennedy has pointed to, the court observed, dealt with an alleged connection between Zyderm and dermatomyositis and a polymyositis-like syndrome, neither of which Kennedy suffers from. Neither Spindler nor anyone else has ever contended in a peer-reviewed journal that Zyderm or any other collagen implant causes "atypical SLE" or SLE. (App., *infra*, p. 18.)

The court noted that Spindler had admitted in his deposition that Kennedy is the only patient he has ever examined who was exposed to Zyderm and developed SLE or "atypical SLE." The court also noted Spindler's admissions that (1) there is no consensus in the rheumatologic community that Zyderm causes SLE, and (2) there are no epidemiological or animal studies demonstrating any link between the two. (App., *infra*, pp. 19-20.)

The court dismissed Spindler's "analogical" hypothesis that Zyderm causes "atypical SLE" in a manner similar to the mechanism involved in drug-induced lupus. Drug-induced lupus has no epidemiological basis, the court found, and neither clinical nor animal studies have demonstrated that the condition even exists. Besides, Spindler has not contended that Kennedy has drug-induced lupus. (App., *infra*, pp. 20-21.)

Because Spindler's testimony failed to meet the requirements of *Daubert I* and *Daubert II* it was, the district court found, inadmissible (App., *infra*, p. 21.)

—

F. THE COURT OF APPEALS' DECISION

The district court abused its discretion, said the Ninth Circuit (Ferguson, Reinhardt, and Thompson). (App., *infra*, p. 4.)

1. Scientific Knowledge

Accepting Spindler's justifications for his opinion at face value, ignoring Spindler's concession that nothing in the medical and scientific literature – and no consensus in the medical and scientific community – associates Zyderm with SLE or "atypical" SLE, and in the complete absence of any independent validation of Spindler's "methodology," the court of appeals concluded:

> Dr. Spindler used the traditional scientific methodology of a clinical medical expert in providing his opinion that Zyderm causes autoimmune disorders, such as atypical SLE.

(App., *infra*, p. 6.) This startling conclusion – not even Spindler was bold enough to assert that his causation theory was based upon "traditional scientific methodology" – has utterly no support in the record.[4] The court of

---

[4] The court of appeals' statement that "[a] scientist for defendant Collagen, Dr. Frank DeLustro, validated Dr. Spindler's methodology" (App., *infra*, p. 7) is simply nonsense. In opposition to Collagen's summary judgment motion,

appeals merely runs through Spindler's laundry list of data and hypotheses (App., *infra*, pp. 5-8) and concludes, without reference to any medical or scientific resource or the evidence of any independent expert, that a causation opinion based upon this material constitutes "scientific knowledge."

The court of appeals thus declares itself and Spindler – in the utter absence of any independent validation – to be the arbiters of sound scientific methodology in this matter. Thus emboldened, the court of appeals joins Spindler's attack on the expertise of the Food and Drug Administration:

> It is understandable why litigants and judges could be skeptical about Dr. Spindler's conclusion. Collagen has been classified by the Food and Drug Administration as a medical device, rather than as a drug. The typical medical devices are pacemakers, heart valves and replacement tissues. . . .
>
> The evidence before us reasonably demonstrates that collagen is not like metal or plastics or other objects usually labeled medical devices. After examining defendant's literature and laboratory tests, Dr. Spindler concludes that collagen should be classified as a drug because it is absorbed by the body. . . . Thus, the analogy between "drug-induced lupus" and collagen-induced lupus is a close one. It is from this foundation that Dr. Spindler seeks to testify.

(App., *infra*, pp. 8-9.)

Kennedy submitted nine pages from Dr. DeLustro's deposition. Nowhere in that testimony is Spindler's "methodology" even mentioned, much less discussed or "validated."

If it is from this foundation that Spindler is to be allowed to testify, one might think there should be a scintilla of evidence in the record that (1) the FDA did not fully understand the nature and function of collagen, (2) the FDA did not fully evaluate the issues discussed by Spindler, (3) the FDA was not aware that collagen is not made of "metal or plastics," and (4) anyone other than Spindler and the court of appeals thinks Spindler's analogy is "a close one."

But there isn't. There is only Spindler's self-validated opinion. This, the court of appeals says, is enough:

> The fact that a cause-effect relationship between Zyderm and lupus in particular has not been conclusively established does not render Dr. Spindler's testimony inadmissible. . . . Dr. Spindler's analogical reasoning was based on objective, verifiable evidence and scientific methodology of the kind traditionally used by rheumatologists. This is precisely what *Daubert* requires.

(App., *infra*, p. 10 (citations omitted).)

There's the crux. Is this really what *Daubert* requires? Or does *Daubert* require more?

It cannot rationally be disputed that there is no evidence – none whatsoever – that Spindler's "analogical reasoning" represents "methodology of the kind traditionally used by rheumatologists." The court of appeals simply made that up. There is no evidence in the record that any competent rheumatologist has ever employed, or would ever employ, Spindler's "analogical reasoning."

So the question is this: Where, as here, (1) it is conceded that a causal connection between exposure and illness has not been established, and (2) a proffered expert, who has done no research on the purported causal connection, proposes to testify to a cause-and-effect relationship based upon his own analytical "methodology," does plaintiff bear the burden of providing independent validation that the expert's "methodology" is accepted as reliable by the relevant medical and scientific community? As discussed below, Collagen submits that the court of appeals' holding that self-validation is sufficient is at odds with the Federal Rules of Evidence, the policies advanced by *Daubert*, and the contrary conclusion reached in other published circuit court decisions.

2. Assisting the Trier of Fact

Under California law – which controls this diversity action – a plaintiff cannot meet her burden of proof on causation unless she presents competent expert testimony demonstrating, to a reasonable degree of medical probability, that Zyderm ***more likely than not*** caused her "atypical" SLE. *Jones v. Ortho Pharmaceutical Corp.*, 163 Cal.App.3d 396 (1985).

> There can be many possible "causes," indeed, an infinite number of circumstances which ***can*** produce an injury or disease. A possible cause only becomes probable when, in the absence of other reasonable causal explanations, it becomes ***more likely than not*** that the injury was a result of its action.

Id. at 403 (emphasis supplied).

Despite being asked repeatedly and directly whether it was his opinion that Zyderm "more likely than not" was the cause of Kennedy's illness, Spindler would not – or could not – express an opinion that meets the standard established by California law. Kennedy's condition "***may be*** caused by" Zyderm, Spindler said, "but with any degree beyond that" he could not express an opinion. There was, Spindler continued, enough evidence "to support that [Zyderm] ***may have*** caused" Kennedy's condition.

Spindler's opinion is facially insufficient to establish causation under California law. Collagen demonstrated that this failure renders Spindler's testimony inadmissible under the second prong of *Daubert*, pursuant to which the district court must determine whether "the proposed expert testimony is 'relevant to the task at hand,' i.e., that it logically advances a material aspect of the proposing party's case." *Daubert II*, 43 F.3d at 1315; *Daubert I*, 509 U.S. at 591.

The court of appeals held, in essence, that *Daubert I* creates a lower standard than that adopted by California, and that *Daubert I* supersedes this element of substantive California law: "The *Daubert* opinions emphasize that causation need not be established to a high degree of certainty for expert testimony to be admissible under Rule 702," the court of appeal said. (App., *infra*, p. 11.) Quoting *Daubert I* to the effect that "there are no certainties in science," the court of appeals found that "Dr. Spindler's testimony clearly meets the [*Daubert I*] requirement, as Dr. Spindler was prepared to testify that based on 'reasonable medical probability' Zyderm caused Mrs. Kennedy's immunological injuries." (App., *infra*, pp. 11-12.)

What Spindler was in fact prepared to testify, as plainly demonstrated in Collagen's briefs and Spindler's own testimony, was that based on "reasonable medical probability" Zyderm ***may have*** caused Kennedy's condition. Whether or not this meets what the court of appeals determined to be the "*Daubert* requirement," it is unquestionably insufficient to meet the requirement of California law.

If the court of appeals is wrong – that is, if California law has not been superseded by some vague standard deduced from *Daubert I* by the court of appeals – then Spindler's testimony was irrelevant and inadmissible under the second prong of *Daubert*, and the district court's judgment in favor of Collagen should have been affirmed.

REASONS FOR GRANTING THE PETITION

A. THE ADMISSIBILITY OF AN UNVALIDATED BOOTSTRAP OPINION IS AN IMPORTANT AND RECURRING ISSUE – UPON WHICH THE LOWER COURTS DISAGREE – LEFT UNRESOLVED BY *DAUBERT* AND *JOINER*

In *Daubert I* the Court ruled that district court judges are charged, under Rule 702, with the duty to act as gatekeepers. That role requires trial court judges to prevent unreliable medical and scientific evidence from reaching juries. "[T]he exclusion of unreliable evidence is a principal objective of many evidentiary rules. *See, e.g.*, Fed. Rule Evid. 702. . . . " *United States v. Scheffer*, ___ U.S. ___, 118 S.Ct. 1261, 1265 (1998). The admissibility of expert testimony, challenged on the basis of scientific

unreliability, is left to the sound discretion of the trial court. *General Electric v. Joiner*, ___ U.S. ___, 118 S.Ct. 512, 517 (1997).

This Court discussed the question of validation in *Daubert I*: "Proposed testimony must be supported by appropriate validation – *i.e.*, 'good grounds,' based on what is known." *Daubert I*, 509 U.S. at 590. But the court did not reach the question raised by this petition: What sort of validation is "appropriate" – constitutes "good grounds" – where the only testimony is from the expert himself? Can the expert self-validate his own methodology? Circuit Judge Kozinski addressed the issue at length in *Daubert II*:

> If the proffered expert testimony is not based on independent research, the party proffering it must come forward with other objective, verifiable evidence that the testimony is based on "scientifically valid principles." . . . [T]he test under *Daubert* is not the correctness of the expert's conclusions but the ***soundness of his methodology***.
>
> . . .
>
> Establishing that an expert's proffered testimony grows out of pre-litigation research or that the expert's research has been subjected to peer review are the two principal ways the proponent of expert testimony can show that the evidence satisfies the first prong of Rule 702. Where such evidence is unavailable, the proponent of expert scientific testimony may attempt to satisfy its burden through the testimony of its own experts. For such a showing to be sufficient, the experts must explain precisely how they went about reaching their conclusions ***and***

> ***point to some external source*** – a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal, or the like – ***to show that they have followed the scientific method***. . . .
>
> Plaintiffs have made no such showing. . . . [P]laintiffs rely entirely on the experts' unadorned assertions that the methodology they employed comports with standard scientific procedures. . . . We've been presented with only the experts' qualifications, their conclusions, and their assurances of reliability. Under *Daubert*, that's not enough.

Daubert II, 43 F.3d at 1317-1319 (emphasis supplied).

> [T]he party proffering the evidence must explain the experts' methodology and demonstrate in ***some objectively verifiable way*** that the expert has both chosen a reliable scientific method and followed it faithfully.

Id. at 1319 n.11 (emphasis supplied).

Applying these principles to one of plaintiffs' experts, Dr. Palmer, the *Daubert II* court said:

> In support of this conclusion [that Bendectin caused plaintiffs' birth defects], Dr. Palmer asserts only that Bendectin is a teratogen and that he has examined the plaintiffs' medical records, which apparently reveal the timing of their mothers' ingestion of the drug. Dr. Palmer offers no tested or testable theory to explain how, from this limited information, he was able to eliminate all other potential causes of birth defects, nor does he explain how he alone can state as a fact that Bendectin caused plaintiffs'

> injuries. . . . "Personal opinion, not science, is testifying here."

Id. at 1319, quoting from *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir. 1992).

Applying the *Daubert II* standard, Spindler's testimony plainly was inadmissible here. Spindler merely related the data he looked at and his conclusion. He may just as well have said he observed that watermelon consumption increases in the summer and deaths by drowning increase in the summer – scientifically verifiable facts – therefore, watermelon consumption causes drowning. Spindler has conducted no research on Zyderm and SLE or "atypical" SLE, pre- or post-litigation. He purports to rely on post-litigation research involving collagen and two diseases other than SLE or "atypical" SLE, but he cites no objective source suggesting such reliance constitutes accepted and reliable scientific methodology.

Spindler's opinion, as both Spindler and the court of appeals concede, is based upon "analogical reasoning" – that is, drawing an analogy between Zyderm/"atypical SLE" and other diseases caused by other exposures, and reaching a conclusion based upon the analogical "model." This, of course, is a concession – as Spindler again readily concedes – that there is nothing which directly links Zyderm with SLE or "atypical" SLE anywhere in the medical or scientific literature.

If there was any support in the medical or scientific community for Spindler's method of "analogical reasoning" – that Spindler had "both chosen a reliable scientific method and followed it faithfully" – then Kennedy must, under *Daubert II*, demonstrate such support "in some objectively verifiable way."

She failed to do so. But this did not trouble the court of appeals. Turning its back on *Daubert II*, the court looked to the District of Columbia Circuit for support. (App., *infra*, p. 10.) In *Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996), *cert. dismissed, Upjohn Co. v. Ambrosini*, ___ U.S. ___, 117 S.Ct. 1572 (1997) plaintiff claimed her birth defects were caused by *in utero* exposure to a prescription drug. The manufacturer moved for summary judgment on the ground that "no reliable scientific evidence existed to support the contention" that the drug caused the defects. (*Id.* at 131.) Plaintiff responded with two opinions – one from an epidemiologist on "general causation" (can the drug cause birth defects?) and another from a teratologist on "specific causation" (did the drug cause this plaintiff's defects?). The district court ruled both opinions inadmissible under *Daubert I* and granted summary judgment.

The court of appeals reversed, finding that the methodology of the teratologist, Dr. Goldman, required no independent validation. *Id.* at 138 & n.12. His self-validation was sufficient. In dissent, Circuit Judge Henderson observed:

> The majority also observes that Goldman himself explained that he used the "traditional methodology of experts in the field." . . . If such conclusory statements must be accepted at face value, as the majority suggests, the *Daubert* standard becomes meaningless.

Id. at 143 (citation omitted) (Henderson, C.J., dissenting.)

The court of appeals' analysis of Spindler's testimony here renders the *Daubert* standard meaningless. If all that is required for admissibility is the expert's unadorned

and self-serving representation that she has employed "scientifically reliable methodology," then the district court has been stripped of its gatekeeper role, and Rule 702's assurance that juries shall receive only scientifically reliable expert testimony is a false and empty promise.

Daubert II, and the courts which agree with and follow its reasoning,[5] give weight and meaning to *Daubert*'s principles by requiring that an expert's methodology be validated in a case – like this one – where the only voice on the question of reliable scientific methodology is that of the expert, testifying on the basis of personal belief in the absence of scientific consensus.

The court of appeal here, and other courts (such as the *Ambrosini* court) that agree with its reasoning,[6] turn

---

[5] *See, e.g., Mitchell v. Gencorp Inc.*, ___ F.3d ___, 1999 WL 5105 (10th Cir. 1999) (expert industrial hygienist expressing opinion on exposure levels must use "techniques subject to objective, independent validation in the scientific community . . . . The expert's assurance that the methodology and supporting data is reliable will not suffice."); *Moore v. Ashland Chemical, Inc.*, 151 F.3d 269 (5th Cir. 1998) (*en banc*) ("the party seeking to have the district court admit expert testimony must demonstrate that the expert's findings and conclusions are based on the scientific method, and, therefore, are reliable. This requires some objective, independent validation of the expert's methodology. The expert's assurances that he has utilized generally accepted scientific methodology is insufficient.")

[6] *See, e.g., McCullock v. H.B. Fuller Co.*, 61 F.3d 1078 (2d Cir. 1995) (doctor's self-validated clinical medical methodology sufficient in the absence of supporting medical literature or hard science); *Zuchowitz v. United States*, 140 F.3d 38 (2d Cir. 1998) (same); *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994), *cert. denied*, 513 U.S. 1190 (1995) (clinical physician's self-validated methodology of differential diagnosis sufficiently

the clock back to the time when courts merely checked to make sure that a witness had the necessary credentials to qualify as an expert, then overruled objections to the expert's methods with the familiar refrain that "it goes to the weight, counsel, not the admissibility."[7]

There is a fundamental and irreconcilable conflict in the published decisions of the circuit courts of appeals on the question of independent validation of the methodology underlying the testimony and opinions of expert witnesses. It is an issue that arises with great frequency in the district courts, and often is – as was the case here – outcome determinative. The bench and bar would benefit greatly from the Court's resolution of this important issue.

---

reliable to support admissibility of causation opinion); *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378 (4th Cir. 1995) (clinician's self-validated medical methodology sufficiently reliable to support causation opinion in the absence of any supporting epidemiological data).

[7] "Judges in jury trials should not exclude expert testimony simply because they disagree with the conclusions of the expert. . . . In arriving at a conclusion, the factfinder may be confronted with opposing experts. . . . But their presence should not preclude the admission of the experts' testimony – they go to the weight, not the admissibility." (App., *infra*, p. 12.) *See also Ambrosini*, 101 F.3d at 131 (district court's exclusion of evidence reversed because of "its failure ultimately to distinguish between the threshold question of admissibility and the persuasive weight to be assigned the expert evidence. . . . ").

B. THERE IS CONFLICT ON THE QUESTION OF WHICH PARTY HAS THE BURDEN OF PROVING THAT AN EXPERT'S TESTIMONY IS BASED ON SCIENTIFICALLY RELIABLE METHODOLOGY

Collagen's summary judgment motion demonstrated that Spindler's own opinion and testimony did not meet the requirements of Rule 702 and *Daubert* for the reasons discussed above. Kennedy responded by referencing the data looked at by Spindler and his ultimate conclusion, without any independent validation of Spindler's "methodology." The court of appeals said:

> [D]efendant Collagen has not introduced any evidence that Dr. Spindler's reasoning is not scientifically valid.

(App., *infra*, p. 10.)

The notion that ***Collagen*** has the burden of proving that Spindler's methodology ***is not*** scientifically reliable turns the burden of proof on its head. "Because plaintiffs bear the ultimate burden of proof on causation, [defendant] had only to point to the absence of a genuine issue of material fact; it wasn't required to produce any evidence at all." *Daubert II*, 43 F.3d at 1315. "The party presenting the expert must show that the expert's findings are based on sound science." *Id.* at 1316. "Plaintiff, as the proponent of the expert testimony, bears the burden of showing that both [*Daubert*] prongs are satisfied." *Sanderson v. IFF*, 950 F.Supp. 981, 993 (C.D. Cal. 1996).[8]

---

[8] Overwhelmingly, the courts that have addressed the issue in the *Daubert* context conclude that the proponent of expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence. *See, e.g., Poust v. Huntleigh*

Until now, federal trial courts have consistently ruled that the proponent of expert testimony bears the burden of proving that the expert's methodology is scientifically reliable. The court of appeal's decision here – suggesting the opponent of expert testimony bears the burden of proving scientific unreliability – will cause great confusion among the district courts facing this frequently occurring issue.

Again, the bench and bar will benefit greatly by the Court's resolution of this issue.

C. THE COURT OF APPEALS WRONGLY HELD THAT *DAUBERT* ESTABLISHES A STANDARD OF CERTAINTY FOR EXPERT OPINIONS THAT SUPERSEDES SUBSTANTIVE STATE LAW

California law is clear: "***Mere possibility alone is insufficient to establish a prima facie case.*** . . . A possible cause only becomes 'probable' when, in the absence of other reasonable causal explanations, it becomes ***more likely than not*** that the injury was a result of its action." *Jones v. Ortho Pharmaceuticals, supra,* 163 Cal.App.3d at 403 (citations omitted, emphasis supplied). This important bedrock principle is well established in California. Numerous authorities have rejected opinions that do not

---

Healthcare, 998 F.Supp. 478, 490 (D. N.J. 1998); *White v. Chicago Pneumatic Tool Co.,* 994 F.Supp. 1478, 1481 (S.D. Ga. 1988); *Dukes v. Illinois Cent. R. Co.,* 934 F.Supp. 939, 946 (N.D. Ill. 1996); *Muzzey v. Kerr-McGee Chemical Corp.,* 921 F.Supp. 508, 509 (N.D. Ill. 1996); *Grimes v. Hoffman-LaRoche, Inc.,* 907 F.Supp. 33, 35 (D. N.H. 1995); *TRW Title Ins. Co. v. Sec. Union Title Ins. Co.,* 890 F.Supp. 756, 758 (N.D. Ill. 1995); *Schmaltz v. Norfolk & Western Ry. Co.,* 878 F.Supp 1119, 1120 (N.D. Ill. 1995).

rise to the more-likely-than-not standard; opinions expressed to a lower degree of certainty are considered speculative and insufficient to sustain the plaintiff's burden of proof.[9] The Ninth Circuit recognized the California rule in *Daubert II*:

> California tort law requires plaintiffs to show that it [Bendectin] ***more likely than not*** caused their injuries.

Daubert II, 43 F.3d at 1320 (emphasis supplied).

Collagen's briefs to the court of appeals carefully set forth the California standard, and demonstrated beyond question that Spindler's evidence – that Zyderm "may have" caused Kennedy's condition – failed to meet that standard as a matter of law. If an expert cannot meet the required level of certainty, his testimony does not "fit" the causation issue and must be excluded under the second *Daubert* prong. *See Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387, 1397-1398 (D. Ore. 1996).

But the court of appeals failed either to articulate the correct standard or to measure Spindler's testimony against the California requirement. Instead, it suggested that *Daubert* established the applicable standard of certainty, and that Spindler's testimony was admissible because it met that standard.

---

[9] *See, e.g., Ochoa v. Pacific Gas & Electric Co.*, 61 Cal.App.4th 1480, 1484-1485 (1998); *Bromme v. Pavitt*, 5 Cal.App.4th 1487, 1498 (1992); *Cottle v. Superior Court*, 3 Cal.App.4th 1367, 1384-1385 (1992); *Dumas v. Cooney*, 235 Cal.App.3d 1573, 1603 (1991); *Zipton v. Workers' Comp. Appeals Bd.*, 218 Cal.App.3d 980, 992 (1990). *See also Memorial Chapel v. Dudler*, 231 Cal.App.3d 190, 196 (1991) (citing *Jones* for the principle that "an issue of fact is not raised by . . . mere possibilities").

The court of appeals says "[t]he second requirement of Rule 702 under *Daubert* is that the expert testimony must assist the trier of fact. The crucial issue in this case is causation." (App., *infra*, p. 11.) Then, rushing past an incomplete and inaccurate statement of the California rule, the court says:

> The *Daubert* opinions emphasize that causation need not be established to a high degree of certainty for expert testimony to be admissible under Rule 702. The Supreme Court stressed that, "[i]t would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science." *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786. On remand, we stated "Not knowing the mechanism whereby a particular agent causes a particular effect is not always fatal to a person's claim. Causation can be proved even when we don't know precisely *how* the damage occurred, if there is sufficiently compelling proof that the agent must have caused the damage *somehow*."

(App., *infra*, pp. 11-12 (court's emphasis).)[10]

---

[10] This passage is curious because neither quotation has anything to do with the issue at hand. The quote from *Daubert I* – the acknowledgment that there are no absolute truths in science – prefaced the finding that ***notwithstanding this fact***, "an inference or assertion must be derived by the scientific method" in order to "qualify as scientific knowledge." *Daubert I*, 509 U.S. at 590. The Court was not talking about "fit" at all, much less establishing a standard for the degree of certainty of an expert opinion. The quote from *Daubert II* is lifted from a discussion of how causation might be proved without understanding of the biological mechanism if there was a high degree of epidemiological proof of causation. Obviously that is

The court of appeals is saying that notwithstanding substantive state law standards, if the district court (or, in this case, the court of appeals supplanting the district court's discretion with its own) believes there is "compelling proof" that the defendant's product "must have caused the damage somehow," then the "fit" prong of *Daubert* is satisfied and the plaintiff's expert's testimony is admissible. In short, even if Spindler's testimony was insufficient as a matter of law under California's standard, it is admissible here because "there are no certainties in science" and the court of appeals believes Zyderm "must have caused the damage somehow."

This is a flagrant usurpation of a fundamental principle of California tort law. The error should be corrected before it metastasizes.

CONCLUSION

The petition for writ of certiorari should be granted.

DATED: March 5, 1999.

Respectfully submitted,

SEDGWICK, DETERT, MORAN & ARNOLD
FREDERICK D. BAKER

Attorneys for Petitioner Collagen Corporation

---

not the case here; if it was, perhaps Spindler could offer an opinion that meets the requirements of California law.

APPENDIX A

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CHARLOTTE KENNEDY and ROBERT KENNEDY, *Plaintiffs-Appellants,* v. COLLAGEN CORPORATION, *Defendant-Appellee.*	No. 97-16945 D.C. No. CV-89-02331-CAL OPINION

Appeal from the United States District Court
for the Northern District of California
Charles A. Legge, District Judge, Presiding

Submitted November 12, 1998*
Pasadena, California

Filed December 7, 1998

Before: Warren J. Ferguson, Stephen Reinhardt, and David R. Thompson, Circuit Judges.

Opinion by Judge Ferguson

---

* The panel unanimously finds this case suitable for decision without oral argument. Fed. R.App. P. 34(a) and Ninth Circuit Rule 34-4.

COUNSEL

Michael M. Essmyer, Essmyer & Hanby, Houston, TX, for plaintiffs-appellants.

Frederick D. Baker, Sedgwick, Detert, Moran & Arnold, San Francisco, CA, for defendant-appellee.

OPINION

FERGUSON, Circuit Judge:

Charlotte and Robert Kennedy brought an action in the district court in 1988 against the Collagen Corporation and its employees for alleged injuries sustained by Mrs. Kennedy following injections with Collagen's medical product, Zyderm. Zyderm is a substance made from the skin, tendons, and connective tissue of bovine animals. A doctor injects Zyderm into facial wrinkles for a smoother appearance. Mrs. Kennedy claims that she developed atypical systemic lupus erythematosus (SLE), a debilitating and incurable autoimmune disease, as a result of the Zyderm injections. Plaintiffs' litigation pleads common law causes of action for negligence, strict liability, breach of express and implied warranty, battery, and conspiracy.

This is the third time this case has been before us after a grant of summary judgment for the defendant. Most recently, we reversed the district court's determination that federal law preempted the state common law causes of action. *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995). In 1992, we also reversed the district court's grant of summary judgment for the defendant and remanded the case. *Kennedy v. Collagen Corp.*, 974 F.2d

1342 (table), 1992 WL 217803 (9th Cir. 1992). The district court had concluded that the affidavit of Dr. Joseph Spindler, who is plaintiffs' expert witness, was insufficient to create a genuine issue of material fact as to whether Zyderm caused Mrs. Kennedy's injuries. The district court determined that the Spindler affidavit raised only a temporal relationship between the injections of Zyderm and Mrs. Kennedy's injuries, that is, that the injuries occurred soon after the injections. This court initially affirmed the grant of summary judgment by the district court. After due consideration of a petition for rehearing, however, we determined that Dr. Spindler based his opinion on other factors in addition to the temporal relationship, and, accordingly, we granted the petition for rehearing, reversed the grant of summary judgment and remanded.

In the meantime, the Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), which held that the *Frye* standard of "general acceptance within the scientific community," under which we had reviewed Dr. Spindler's affidavit, was superseded by Federal Rule of Evidence 702. In April of 1997, Collagen Corporation filed their third motion for summary judgment, alleging that the Kennedys' expert testimony as to causation was inadmissible under *Daubert*. The district court reviewed Dr. Spindler's affidavit under *Daubert*, found it inadmissible, and once again granted summary judgment to the defendant. This issue is now before us on appeal.

We review the district court's decision to exclude expert scientific testimony for abuse of discretion, even in the context of a summary judgment motion. *See General*

Electric Co. v. Joiner, ___ U.S. ___, 118 S.Ct. 512, 519 (1997). We conclude that the district court improperly applied the *Daubert* test, because it failed to consider relevant scientific evidence relied on by the plaintiffs' expert witness, Dr. Spindler, to support his conclusion.[1] Thus, the court abused its discretion in excluding his testimony. We hold that, because plaintiffs adduced enough admissible evidence to create a genuine issue of material fact as to whether Zyderm caused Mrs. Kennedy's atypical SLE, the district court erred in granting summary judgment to defendant.

Discussion

I. *Daubert*

Daubert established that, faced with a proffer of expert scientific testimony, the trial judge, in making the initial determination whether to admit the evidence, must determine whether the expert's testimony reflects (1) "scientific knowledge," and (2) will assist the trier of fact

---

[1] Plaintiffs argue that because Dr. Spindler is a medical expert, rather than a scientific expert, *Daubert's* requirement of scientific validity is not applicable here. This court, after *Daubert*, has held that a medical doctor's testimony regarding the cause of an injury may be based on experience and review of medical records only. *See Sementilli v. Trinidad Corp.*, No. 96-16034, slip op. 12865, 12879 (9th Cir. filed Sept. 16, 1998) (as amended Nov. 12, 1998) (per curiam). However, in this case, involving the injection of a substance by a medical doctor for medical reasons, we will follow the uniform practice among courts in judging the admission of clinical medical testimony by the *Daubert* standard. *See, e.g., Moore v. Ashland Chemical, Inc.*, 151 F.3d 269 (5th Cir. 1998) (en banc).

to understand or determine a material fact at issue. 509 U.S. at 592. This requires "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. The Court stated that many factors will bear on this inquiry. For example, a judge may consider whether the theory has been subjected to peer review and publication, although in some instances well-grounded but innovative theories will not have been published, and, thus, should not be excluded on this basis alone. *Id.* at 593. The Court emphasized that the focus of the inquiry envisioned by Rule 702 must be on the principles and methodology underlying an expert's testimony, not on the conclusions. *Id.* at 506. The Court later refined this language, explaining that a district judge may reject expert testimony where the "analytical gap" between the data and the expert's conclusion is too great. *Joiner*, 118 S.Ct. at 519.

When the Supreme Court remanded *Daubert* to this court, we added that, where the proffered testimony is not based on independent research, in order to be admissible as "scientific knowledge," it must be supported by "objective, verifiable evidence that the testimony is based on 'scientifically valid principles.'" *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995).

II. Scientific Knowledge

Dr. Spindler relied upon a wide variety of objective, verifiable evidence in forming his opinion that Zyderm

causes autoimmune disorders such as atypical SLE: (1) peer-reviewed articles; (2) clinical trials and product studies conducted by the defendant; (3) the Texas Department of Health's investigation; (4) his examination of Mrs. Kennedy; (5) Mrs. Kennedy's medical history; (6) Mrs. Kennedy's medical laboratory tests; and (7) Mrs. Kennedy's medical reports.[2] The district court, in rejecting Dr. Spindler's testimony, determined that the testimony was not based on scientific reasoning, because it focused on the lack of specific studies proving Zyderm causes lupus, and the absence of consensus in the medical community on this point. In doing so, however, the district court ignored the scientific studies relied upon by Dr. Spindler that reinforce the validity of the *methodology* Dr. Spindler relied upon in reaching his conclusion. Ultimately, the trial court failed to distinguish between the threshold question of admissibility of expert testimony and the persuasive weight to be accorded such testimony by a jury.

Dr. Spindler used the traditional scientific methodology of a clinical medical expert in providing his opinion that Zyderm causes autoimmune disorders, such as atypical SLE. In particular, he relied on the finding, established in both peer-reviewed publications and clinical studies, that Zyderm induces the body to produce the same autoimmune antibodies that are the hallmark of autoimmune diseases like SLE. An independent study by researchers in San Diego concluded that bovine collagen – Zyderm's

---

[2] We note, as a preliminary matter, that the parties do not dispute that Dr. Spindler, who is a rheumatologist, is an expert in lupus, autoimmune diseases, and immunological conditions.

active ingredient – can induce autoantibodies. Dr. Spindler co-authored a peer-reviewed publication describing a scientific relationship between Zyderm collagen injections and the development of autoimmune reactions and autoantibodies. These reactions accompany autoimmune diseases known as dermatomyositis and polymyositis-like syndrome. A scientist for defendant Collagen, Dr. Frank DeLustro, validated Dr. Spindler's methodology. Furthermore, Collagen Corporation's own clinical trials reveal that numerous patients develop autoantibody reactions following bovine collagen injections. Finally, the Texas Department of Health investigated collagen injections in about 40 reported cases of autoimmune reactions from the product, and found varying temporal relationships between collagen injections and the onset of autoimmune diseases.

In addition to these scientific and clinical studies of the connection between collagen and autoimmune disorders, Dr. Kennedy's opinion relied on a physical examination of Mrs. Kennedy and a review of her extensive medical history and records, including laboratory tests. Mrs. Kennedy's history and medical records reveal that, prior to the injections of defendant's collagen product, she was free of lupus or any other autoimmune disease. After the third injection of Zyderm, Mrs. Kennedy suffered a severe adverse reaction and was diagnosed as having an atypical form of SLE.[3] Mrs. Kennedy's body produced autoantibodies following her injections with

---

[3] Physicians identify "atypical SLE" when a patient does not meet all of the criteria required for an official diagnosis of SLE.

Zyderm, such as those produced by patients suffering from lupus. Physicians recognize lupus as an incurable autoimmune disease set off when something goes wrong with the body's immune system and antibodies that normally fight germs begin to attack healthy tissue. Mrs. Kennedy also produced elevated levels of antihistone antibodies, which are commonly found in patients with a condition known as "drug-induced lupus," a disease accepted in the medical community, in which lupus-type symptoms develop after exposure to certain medications.

It is understandable why litigants and judges could be skeptical about Dr. Spindler's conclusion. Collagen has been classified by the Food and Drug Administration as a medical device, rather than a drug. The typical medical devices are inert objects such as pacemakers, heart valves and replacement inserts. The substances comprising such devices are not absorbed or metabolized by a person's body. To claim that such inert objects may cause lupus surely would be "junk science." Even the Kennedys recognize that if parts of collagen are not metabolized, then collagen likely is not the cause of Mrs. Kennedy's injuries. Their complaint alleges that collagen is a drug, chemical, or compound.

The evidence before us reasonably demonstrates that collagen is not like metal or plastics or other objects usually labeled medical devices. After examining defendant's literature and laboratory tests, Dr. Spindler contends that collagen should be classified as a drug because it is absorbed by the body. The body breaks down the collagen fibers into amino acids, which are then metabolized into the body. The Texas Department of Health agrees that Zyderm could have been classified as a drug

since it achieves its intended purpose through a chemical reaction. Furthermore, the defendant ran laboratory tests that showed such a reaction, as have other researchers, who have concluded that, after multiple injections, collagen can induce autoantibodies. Thus, the analogy between "drug-induced lupus" and collagen-induced lupus is a close one. It is from this foundation that Dr. Spindler seeks to testify.

The district court, in rejecting Dr. Spindler's testimony, emphasized that no epidemiological or animal studies link Zyderm to SLE or atypical SLE. Other circuits, however, have found that it is scientifically permissible to reach a conclusion on causation without these types of studies. *See, e.g., Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1384 (4th Cir. 1995) (finding, under *Daubert*, that expert testimony need not be based on epidemiological data or identical case studies to prove causation). Here, Dr. Spindler explained that epidemiological studies linking an increased incidence of SLE to patients injected with collagen would be almost impossible to perform because patients who have collagen injections normally do not seek treatment from rheumatologists for their reactions. Patients who have collagen injections usually consult the injecting doctor when any subsequent problems arise. Because the injecting doctor typically is a plastic surgeon or dermatologist, he is not trained to recognize autoimmune or immune disorders. Thus, the causal connection goes unrecognized.

Other circuits have allowed clinical medical experts to testify to an opinion on causation as long as it is based on methods reasonably relied on by experts in their field. *See, e.g., Zuchowicz v. United States*, 140 F.3d 381, 387 (2d

Cir. 1998) (accepting the district court's conclusion that plaintiff's experts based their opinions on such methods). Here, based on his knowledge of the connection between collagen and various autoimmune disorders, combined with his observation of Mrs. Kennedy's injuries and her medical history and laboratory tests, Dr. Spindler concluded that Zyderm, a collagen product, had caused Mrs. Kennedy's particular auto-immune disorder, atypical SLE. The fact that a cause-effect relationship between Zyderm and lupus in particular has not been conclusively established does not render Dr. Spindler's testimony inadmissible. *See Ambrosini v. Labarraque*, 101 F.3d 129, 139 (D.C. Cir. 1996), *cert. dismissed, Upjohn Co. v. Ambrosini*, ___ U.S. ___, 117 S.Ct. 1572 (1997) (reversing district court's finding that expert testimony was inadmissible because none of the studies relied upon specifically concluded that Depo-Provera caused the type of birth defects suffered by the plaintiff). Dr. Spindler set forth the steps he took in arriving at his conclusion in his deposition. Dr. Spindler's analogical reasoning was based on objective, verifiable evidence and scientific methodology of the kind traditionally used by rheumatologists. This is precisely what *Daubert* requires. *See, e.g., Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1125 (9th Cir. 1994) (finding admissible expert testimony of a rheumatologist based on medical records, his clinical experience, preliminary results of an epidemiological study and medical literature). We note also that defendant Collagen has not introduced any evidence that Dr. Spindler's reasoning is not scientifically valid. *See Ambrosini*, 101 F.3d at 139 (noting that lack of contradictory evidence supported admissibility of expert's opinion regarding causation).

Although the district court properly may exclude expert testimony if the court concludes too great an analytical gap exists between the existing data and the expert's conclusion, here the gap was of the district court's making. The court did not consider all of the data relied upon by Dr. Spindler, namely, studies by the defendant and others finding that Zyderm can induce autoimmune reactions. Consequently, the court abused its discretion in concluding that Dr. Spindler's testimony failed to meet *Daubert's* scientific knowledge requirement.

III. Assisting the Trier of Fact

The second requirement of Rule 702 under *Daubert* is that the expert testimony must assist the trier of fact. The crucial issue in this case is causation. As we noted in our unpublished opinion in this case, California law provides the substantive standard governing proof of causation in personal injury cases. *Kennedy,* 1992 WL 217803, at *1. The Kennedys must prove causation "within a reasonable medical probability based upon competent expert testimony." *Jones v. Ortho Pharmaceutical Corp.,* 163 Cal. App.3d 396, 402 (1985).

The *Daubert* opinions emphasize that causation need not be established to a high degree of certainty for expert testimony to be admissible under Rule 702. The Supreme Court stressed that, "[i]t would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science." *Daubert,* 509 U.S. at 590. On remand, we stated: "Not knowing the mechanism whereby a particular agent causes a particular effect is not always fatal to a

plaintiff's claim. Causation can be proved even when we don't know precisely *how* the damage occurred, if there is sufficiently compelling proof that the agent must have caused the damage *somehow." Daubert*, 43 F.3d at 1314.

Dr. Spindler's proffered testimony clearly meets the requirement, as Dr. Spindler was prepared to testify that based on "reasonable medical probability" Zyderm caused Mrs. Kennedy's immunological injuries.

IV. Conclusion

Judges in jury trials should not exclude expert testimony simply because they disagree with the conclusions of the expert. The *Daubert* duty is to judge the reasoning used in forming an expert conclusion. The test is whether or not the reasoning is scientific and will assist the jury. If it satisfies these two requirements, then it is a matter for the finder of fact to decide what weight to accord the expert's testimony. In arriving at a conclusion, the fact-finder may be confronted with opposing experts, additional tests, experiments, and publications, all of which may increase or lessen the value of the expert's testimony. But their presence should not preclude the admission of the expert's testimony – they go to the *weight*, not the admissibility. As one court has summarized:

> Disputes as to the strength of [an expert's] credentials, faults in his use of [a particular] methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony.

McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1044 (2d Cir. 1995).

We conclude that the district court failed to consider all of the reasoning or methodology relied on by Dr. Spindler in linking Zyderm to Mrs. Kennedy's illness and, thus, erred in finding that Dr. Spindler's testimony was not supported by scientific evidence. Because Dr. Spindler's testimony is supported by scientific evidence and will assist the trier of fact, we hold that, his testimony is admissible under Rule 702. Thus, reviewing the defendant's summary judgment motion de novo, we reverse the district court's grant of summary judgment in favor of defendant. The district court at trial must admit the testimony and evidence of Dr. Spindler.

REVERSED and REMANDED.

APPENDIX B

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CHARLOTTE KENNEDY and ROBERT KENNEDY,

Plaintiffs,

v.

COLLAGEN CORPORATION

Defendant.

No. C 89-2331-CAL.

ORDER FOR SUMMARY JUDGMENT

(Filed Jun. 26, 1997)

In 1982 plaintiff Charlotte Kennedy was treated by her doctor with defendant Collagen Corporation's Zyderm Collagen Implant. She claims to have subsequently developed atypical systemic lupus erythematosus ("atypical SLE"). She alleges causes of action for negligence, strict liability, breach of express and implied warranty, battery, and conspiracy against Collagen. Her husband, plaintiff Robert Kennedy, alleges a cause of action for loss of consortium.

Defendant moves for summary judgment, arguing that plaintiffs have not presented any admissible evidence from which a jury can find that Zyderm caused Ms. Kennedy's atypical SLE.

I.

Plaintiffs' expert witness on the issue of causation is Dr. Joseph Spindler. He is the *only* witness who is offered

by plaintiffs to testify that Zyderm caused Ms. Kennedy's condition. Dr. Spindler last examined Ms. Kennedy in 1990, and his affidavit was filed by plaintiffs in opposition to a motion for summary judgment by defendant in 1990. In his affidavit, Dr. Spindler states that:

> Mrs. Kennedy's medical history, records and current laboratory results are consistent with a temporal relationship between her injections and her medical condition, including a severe adverse reaction to Defendant's product, with systemic immune disorders and deteriorating medical condition and clinical symptoms. . . .
>
> Based on reasonable medical probability, Mrs. Kennedy suffered a definite adverse systemic immunological reaction to the bovine collagen injections, which injections triggered her systemic immunological injuries. This systemic immunological reaction has caused and was a substantial factor, if not the factor, in causing a changing immunological picture for Mrs. Kennedy; and with the temporal relationship, it appears the injections acted as a trigger in the development and progression of her evolving systemic-immune condition and disorders.

II.

In 1990 this court granted summary judgment for defendant, finding that Dr. Spindler's affidavit was insufficient to create a genuine issue of material fact on causation, because it identified only a "temporal relationship." "[T]emporal priority does not establish causal force: it is a logical fallacy to reason *post hoc, ergo propter hoc.*" *People v. Benson*, 52 Cal.3d 754, 781 (1990); *see also Hardt v.*

Heidweyer, 152 U.S. 547, 558 (1894) (noting that "the rule of causation implies some other sequence than that of time").

The Ninth Circuit initially affirmed this court's grant of summary judgment, but then reversed and remanded after a petition for rehearing, holding that Dr. Spindler's affidavit created a genuine issue of material fact on causation. The Ninth Circuit rejected the contention that Spindler's opinion is based predominantly on the "temporal relationship" between Ms. Kennedy's treatment with Zyderm and her disease, stating that: "The district court was inaccurate in believing that Dr. Spindler's opinion was based primarily on the temporal relationships between the Zyderm injections and Kennedy's injuries. . . . " *Kennedy v. Collagen Corp.*, No. 91-15597, 1992 WL 217803, *3 (9th Cir. Sept. 8, 1992). The court held that Dr. Spindler's affidavit established the existence of a genuine issue of material fact regarding causation and was sufficient to preclude summary judgment. *Id.* at *1, *3, and *3 n.2.

III.

After the Ninth Circuit's decision in this case, the United States Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) (hereinafter "*Daubert I*"), which explained that Federal Rule of Evidence 702 governs the admissibility of expert scientific testimony. Under *Daubert I*, federal judges must make two determinations in order to find expert scientific testimony admissible: (1) that the testimony reflects "scientific knowledge," which the Court defined as "derived by

the scientific method," *Id.* at 509; and (2) that the evidence has "a valid scientific connection to the pertinent inquiry," sometimes described as the requirement of "fit." *Id.* at 591-592.

The Ninth Circuit did not analyze the admissibility of Dr. Spindler's testimony under that standard when it decided this case on appeal. Defendant again moves for summary judgment, arguing that plaintiffs have not created a genuine dispute as to any material fact on the issue of whether Zyderm caused plaintiff's injury under the *Daubert I* standard. Because *Daubert I* and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995) (hereinafter "*Daubert II*"), have changed the legal standard by which federal courts should determine the admissibility of expert scientific testimony, this court reexamines the admissibility of Dr. Spindler's opinion under that standard. Dr. Spindler's opinion is still as defined in his 1990 affidavit. Dr. Spindler has offered no additional affidavit. And his deposition, taken in 1997, states no additional scientific basis under the first step of *Daubert I* for his opinion on causation.

In *Daubert I*, the Supreme Court discussed several factors relevant to the court's inquiry into whether offered expert scientific testimony satisfies the first step under Fed.R.Evid. 702, including: whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it has been subjected to peer review and publication; whether it can be and has been tested; and whether the known or potential rate of error is acceptable. *Id.* at 593-594 (noting also that "we do not presume to set out a definitive checklist or test").

The Ninth Circuit's decision on remand in *Daubert II* added that judges should examine whether the expert is testifying about matters growing naturally out of his research, or whether he has developed his testimony expressly for the purpose of testifying. *Id.* at 1317. Where, as here, the proffered expert testimony is not based on independent research, "the party proffering it must come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.' " *Id.* at 1317-1318. This can be accomplished by presenting evidence of peer review. *Id.* at 1318.

Plaintiffs cite an article co-authored by Dr. Spindler. Jean Cukier, M.D., et al., *Association Between Bovine Collagen Dermal Implants and Dermatomyositis or a Polymyositis-Like Syndrome,* 118 Annals of Internal Med. 920 (1993). That study, however, dealt with patients who developed dermatomyositis or a polymyositis-like syndrome, not atypical SLE, after exposure to Zyderm. It is undisputed that Ms. Kennedy did not develop either of those conditions and that atypical SLE is a different autoimmune disorder. Neither Dr. Spindler, nor any other member of the scientific community, has contended in a peer-reviewed journal that Zyderm or any other collagen implant causes SLE or atypical SLE. In Daubert II, as in this case:

> the only review the plaintiff's experts' work has received has been [in litigation]. . . . Despite the many years the controversy has been brewing, no one in the scientific community – except [plaintiffs'] experts – has deemed these studies worthy of verification, refutation or even comment. It is as if there were a tacit understanding

> within the scientific community that what's going on here is not science at all, but litigation.

Daubert II, 43 F.3d at 1318.

The *Daubert II* court noted that if plaintiffs cannot present evidence that the expert's testimony grows out of pre-litigation research or that the research has been subjected to peer review, the experts themselves may "explain precisely how they went about reaching their conclusions and point to some objective source . . . to show that they have followed the scientific method as it is practiced by (at least) a recognized minority of scientists in their field." *Id.* at 1319.

Defendant challenges Dr. Spindler's methodology, arguing that his hypothesis about causation is untested and based on this single case of Ms. Kennedy. With regard to the scientific validity of case reports, this court said in *Casey v. Ohio Medical Products*, 877 F.Supp. 1380 (N.D.Cal. 1995), that: "case reports are not reliable scientific evidence of causation, because they simply describ[e] reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation." *Id.* at 1385; *see also Pick v. American Medical Systems*, 958 F.Supp. 1151, 1161 (E.D.La. 1997) (noting that "courts have frequently rejected case studies as an insufficient basis to decide causation when they lack control groups").

Dr. Spindler testified in his deposition that Ms. Kennedy is the only patient he has ever examined who had exposure to Zyderm and also developed SLE or atypical

SLE. He admits that there is no consensus in the rheumatologic community that Zyderm causes SLE, that neither he nor anyone else has performed any epidemiological studies to determine whether Zyderm causes SLE, that no study in the peer-reviewed literature indicates that Zyderm causes SLE, and that no animal studies exist linking Zyderm to SLE.

In a similar case, *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387 (D.Or. 1996), the plaintiffs alleged that the defendants' breast implants caused atypical connective tissue disease ("ACTD"). Like atypical SLE, the relevant medical community did not generally accept the existence of ACTD as of the date of the plaintiffs' experts' opinions. Further, as in this case, ACTD had no specific diagnostic test and no signature disorder. The Hall court concluded that: "Because ACTD is at best an untested hypothesis, there is no scientific basis for any expert testimony as to its causes and presence in plaintiffs." *Id.* at 1402. The court granted the defendants' motions to exclude the plaintiff's expert's testimony.

Dr. Spindler did testify in his deposition that there is some evidence that Zyderm can stimulate the immune system to produce autoantibodies which may then play a role in causing SLE or atypical SLE. He compared his hypothesis about Ms. Kennedy's condition to an accepted rheumatological condition called "drug-induced lupus," in which a patient will develop SLE after exposure to certain medications, and the symptoms will improve after removal of the irritating substance. Drug-induced lupus is a condition that apparently has no epidemiological basis, and no clinical or animal studies have been done to demonstrate its existence. Dr. Spindler does not contend

that Ms. Kennedy has drug-induced lupus, but only that her exposure to Zyderm may have caused her present condition by a mechanism similar to that which causes drug-induced lupus.

Notwithstanding Dr. Spindler's comparison of atypical SLE to drug-induced lupus, *none* of the various factors discussed in *Daubert I* and *Daubert II* weigh in favor of a finding that Dr. Spindler's testimony is based on "scientifically valid principles." Accordingly, Dr. Spindler's testimony is inadmissible because it fails to satisfy the first step of the required analysis under Fed.R.Evid. 702. This court therefore need not discuss the second step.

IV.

Dr. Spindler's testimony is inadmissible under Rule 702 because it is not based on the scientific inquiry required by the first step of *Daubert I*. This court therefore GRANTS defendant's motion for summary judgment, because without Dr. Spindler's testimony, the only offered evidence on causation, plaintiffs will not be able to establish their prima facie case at trial. And the absence of causation is fatal to all of plaintiffs' alleged causes of action.

IT IS SO ORDERED.

Dated: June 26 1997.

/s/ Charles A. Legge
CHARLES A. LEGGE
United States District Judge

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 94-15197

D.C. No. CV-89-02331-CAL

CHARLOTTE KENNEDY and ROBERT L. KENNEDY,

Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of California
Charles A. Legge, District Judge, Presiding

Argued and Submitted
August 8, 1995 – Pasadena, California

Filed October 17, 1995

Before: Warren J. Ferguson, Stephen Reinhardt
and David R. Thompson, Circuit Judges.

Opinion by Judge Ferguson;
Concurrence by Judge Reinhardt

OPINION

FERGUSON, Circuit Judge:

In this appeal, Charlotte and Robert Kennedy challenge the district court's grant of summary judgment in favor of defendant, Collagen Corporation ("Collagen"). The Kennedys contend that their state common law

claims are not preempted by the Medical Device Amendments of 1976 ("the MDA"), 21 U.S.C. §§ 360c-360l (Supp.1995), and that genuine issues of material fact remain in issue in their suit against Collagen. We reverse the district court and remand for trial.

I. BACKGROUND

This action arises out of Charlotte Kennedy's treatment with Zyderm Collagen Implant ("Zyderm"), a prescription medical product manufactured by defendant Collagen. Zyderm is used by physicians to treat soft tissue defects of the skin caused by disease, trauma, congenital defects, or aging. Following Charlotte Kennedy's treatment with Zyderm, she developed systemic lupus erythematosus ("SLE"), an autoimmune disease.

Upon contracting SLE, Charlotte and Robert Kennedy brought suit against Collagen alleging negligence, strict liability, breach of warranty, battery, conspiracy and loss of consortium. Based on the Kennedys' failure to present sufficient evidence of causation, the district court granted Collagen's original motion for summary judgment. This Court affirmed the decision of the district court in June 1992, but later granted the Kennedys' petition for rehearing, withdrew its earlier decision and reversed the district court. *Kennedy v. Collagen*, 967 F.2d 587 (9th Cir. 1992), *withdrawn*, 974 F.2d 1342 (9th Cir. 1992), *cert. denied*, ___ U.S. ___, 113 S.Ct. 3037 (1993).

The present appeal stems from Collagen's motion for summary judgment filed on remand to the district court. In its second motion for summary judgment, Collagen

asserts that all of the Kennedys' claims are preempted by the MDA, 21 U.S.C. § 360k(a). The district court granted Collagen's motion, finding that the Kennedys' claims are preempted under § 360k(a). This appeal timely followed.

On appeal, the Kennedys make two arguments. First, they contend that § 360k(a) only preempts state law to the extent that state law establishes additional or divergent requirements for a *particular* medical device. Because neither the state common law nor the FDA has established any *specific* requirements unique to Zyderm, the Kennedys assert, their state common law claims are not preempted. In addition, the Kennedys assert that the state common law, pursuant to which they are suing, is a law of general applicability and therefore specifically not preempted by the MDA.

II. DISCUSSION

I. *Standard of Review*

This court reviews the district court's grant of summary judgment on a pure question of law, in which there are no disputed facts, *de novo*. *Turner v. Prod*, 707 F.2d 1109, 1114 (9th Cir. 1983).

II. *History of The MDA*

The MDA was enacted largely in response to the public outcry following the injuries suffered in the 1960s and early 1970s by women using the Dalkon Shield contraceptive device. *See Ministry of Health v. Shiley*, 858 F.Supp. 1426, 1434 (C.D. Cal. 1994). Federal investigations in the wake of the Dalkon Shield injuries confirmed that

the "pace of the [medical device] industry far exceeded the FDA's ability to control it." *Id.* at 1434 (quoting Susan Barlett Foote, *Loops and Loopholes: Hazardous Device Regulation Under the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act*, 7 ECOLOGY L.Q. 101, 102-103 (1978)).

Congress subsequently passed the MDA in order "to assure the reasonable safety and effectiveness of medical devices intended for human use." H.Conf.Rep. No. 1090, 94th Cong., 2d Sess. *reprinted in* 1976 U.S. Code Cong. & Admin. News 1070, 1103. The MDA gives the FDA broad powers to classify and regulate medical devices. Under the MDA, the FDA must assign a medical device to one of three statutorily delineated categories. Class I devices are those devices which pose little or no threat to public health. They are subject to only general requirements concerned with their manufacture. Tongue depressors are one example of a Class I medical device. *See* 21 U.S.C. § 360c(a)(1)(A); 21 C.F.R. § 860.3(c)(1). Class II devices include items such as tampons and oxygen masks. Use of Class II devices involves some risk of injury and, as a result, the FDA establishes performance standards, post-market surveillance programs and guidelines for their use. *See* 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 860.3(c)(2).

Class III devices are those devices which are implanted in the body or which pose a potentially unreasonable risk of injury. *See* 21 U.S.C. § 360c(a)(1)(C); 21 C.F.R. § 860.3(c)(3). They include Zyderm, as well as pacemakers, heart valves and replacement joints. Because of their inherent dangerousness, Class III devices are subject to the most stringent FDA regulation. All Class III devices are required to obtain premarket approval prior

to being released for sale and use. 21 U.S.C. § 360e; 21 C.F.R. § 814.1(c).

In order to attain premarket approval, the manufacturer of a Class III device must submit all of its information on any investigations concerning the device's safety or effectiveness, a statement of the intended use of the product, a description of the expected manufacturing process, and any other requested information to the FDA. 21 U.S.C. §§ 360e(c)(1)(A)-(G); 21 C.F.R. §§ 814.20(b)(2)-(12). Prior to approval by the FDA, the existence of an application for approval may not be publicly disclosed unless it has previously been publicly disclosed or acknowledged. 21 C.F.R. § 814.9(b). There is no opportunity for public comment or for any public challenge to the information presented to the FDA by the device manufacturer.

III. GENERAL PREEMPTION PRINCIPLES

The principle of federal preemption of state law derives from Article VI of the Constitution, the Supremacy Clause. Article VI establishes the laws of the United States as "the supreme Law of the Land . . . any Thing in the constitution or Laws of any state to the Contrary notwithstanding." Art. VI, cl. 2.

Federal law can preempt state law in one of two ways. Congress may either explicitly state its intent to preempt state law in the language of a statute or Congress may imply its intent to preempt through the structure and purpose of a statute. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Implicit preemption can itself

take two forms. Congress may either occupy a field by passing a statutory scheme so extensive that it covers an entire legislative field or Congress may enact a federal law which makes compliance with a state law impossible. *Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

Where Congress has made its intent to preempt explicit in a statute, the Supreme Court has held that:

> 'there is no need to infer congressional intent to preempt state laws from the substantive provisions' of the legislation . . . Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not preempted.

Cipollone v. Liggett Group, Inc., ___ U.S. ___, 112 S.Ct. 2608, 2618 (1992) (citations omitted). Therefore, the question to be answered in instances of express preemption is the *extent* to which Congress intended to preempt state law.

Regardless of the form preemption takes, the Supreme Court has consistently imposed a strong presumption against preemption.

> Consideration of issues arising under the Supremacy Clause 'start with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.'

Cipollone, 112 S.Ct. at 2617 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). In its most recent decision on preemption, the Supreme Court held that the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq. (1988 ed. and Supp.

V), did not preempt a New York law requiring hospitals to add "surcharges on bills of patients whose commercial insurance coverage is purchased by employee health-care plans governed by ERISA, and [requiring] . . . surcharges on HMOs, insofar as their membership fees are paid by an ERISA plan." N.Y. *Conference of Blue Cross v. Travelers Ins.*, ___ U.S. ___, 115 S.Ct. 1671, 1673-74 (1995). In *N.Y. Conference*, the Court reaffirmed that even a preemption provision in an expansive statutory scheme such as ERISA must be read narrowly, especially in areas of historic state concern such as health and safety. *Id.* at 1676.

Similarly, in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), the Court applied the presumptions against preemption to uphold a state punitive damage award in the face of comprehensive federal legislation addressing nuclear safety. In *Silkwood*, the Court noted the tension its holding created between federal legislation to regulate nuclear safety and a state's ability to impose its own laws of liability; however, the Court was reluctant to find complete preemption in the face of congressional silence with regard to tort remedies. "It is difficult to believe that Congress would, without comment, remove all means of recourse for those injured by illegal conduct." *Silkwood*, 464 U.S. at 251.

IV. PREEMPTION UNDER THE MDA

Congress explicitly provided for the preemption of state law under the MDA. Section 360k(a) establishes that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect

> to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Some courts have read the language as creating an expansive federal preemption of state law. The Eighth Circuit, for example, has read the language of § 360k(a) to preempt *any* state tort claims dealing with safety, effectiveness or any other aspect governed by the FDA's pre-market approval process.[1] *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994).

However, the statutory language of § 360k(a) does not create the broad, sweeping preemption found by the Eighth Circuit. Reading § 360k(a)(1) broadly requires recognizing that *any* state law is, by definition, a law "in addition to" federal law. A broad reading of § 360k(a) thus renders the "different from" language meaningless

---

[1] In *Anguiano v. E.I. Du Pont De Nemours & Co., Inc.*, 44 F.3d 806 (9th Cir. 1995), we held that state tort law was not preempted with respect to the Class II device in question. *Id.* at 810. Our reason was that there were no federal requirements applicable to the device. *Id.* In dictum, we expressed the view that in promulgating the MDA, Congress intended to preempt state tort law. *Id.* at 809. It is obvious from what we held in *Anguiano* that the dictum was either overbroad or not intended to be taken literally. In any event, upon careful analysis, we believe that the dictum was not correct.

and forces a strained reading of the statute. Similarly, in *N.Y. Conference*, the Supreme Court held that the term "relate[s] to" is potentially unbounded if interpreted broadly. If it "were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for '[r]eally, universally, relations stop nowhere.' " *N.Y. Conference*, 115 S.Ct. at 1677 (citations omitted). Therefore, the Court held that in order to define "relate[s] to" in a meaningful manner, a court must look to the purpose and effects of the state law in issue. *Id.* at 1676.

We must address two threshold questions: (1) what constitutes a "State . . . requirement" and (2) what constitutes a "requirement" under the MDA. *Lohr v. Medtronic*, 56 F.3d 1335, 1342 (11th Cir. 1995). Congress has not addressed these precise questions. Therefore, we must look to the FDA's understanding of the scope of the MDA's statutory preemption provision since the FDA is the agency charged by Congress with implementing the MDA. An agency's interpretation of its own statute is controlling so long as not contrary to Congress' intent. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984). As long as the FDA has propounded any "reasonable interpretation" of the provision, this Court has no cause to overturn the agency's interpretation in favor of its own. *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945).

The FDA interprets § 360k(a) in 21 C.F.R. § 808.1(d). Section 808.1(d) provides:

> State or local requirements are preempted *only* when the Food and Drug Administration has established *specific* counterpart regulations or

> there are other *specific* requirements applicable to a *particular* device under the act, thereby making any existing divergent State or local requirements applicable to the device different from or in addition to, the *specific* Food and Drug Administration requirements . . .

21 C.F.R. § 808.1(d) (emphasis added). Section 808.1(d) goes on to delineate other state and local requirements which affect medical devices, but which are not preempted by § 360k(a):

> (1) Section 521(a) does not preempt State or local requirements of *general applicability* where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices . . .
>
> (6)(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices . . .

21 C.F.R. § 808.1(d)(1)-(9) (emphasis added). Section 808.1(d) explicitly requires that state or local requirements *only* be preempted where there exist *specific* counterpart requirements or regulations applicable to a *particular* device.

Defendants contend and the district court agreed that the premarket approval process required by the FDA for Class III devices constitutes a *specific* federal requirement which preempts state common law claims. Other courts addressing the question of the preemptive scope of the MDA have devoted considerable analysis to the issue of whether the premarket approval process is specific

enough to satisfy the FDA's narrow preemption rule. *See e.g., Martello,* 42 F.3d at 1169; *Stamps v. Collagen Corp.,* 984 F.2d 1416, 1421-22 (5th Cir.), *cert. denied,* ___ U.S. ___, 114 S.Ct. 86 (1993). Courts have also expostulated on whether state common law claims are of specific enough applicability to escape the FDA's pronouncement that laws of general applicability are not preempted. *See e.g., Michael v. Shiley,* 46 F.3d 1316, 1323 (3rd Cir. 1995); *King v. Collagen Corp.,* 983 F.2d 1130, 1136 (1st Cir.), *cert. denied,* ___ U.S. ___, 114 S.Ct. 84 (1993).

While most courts have found that at least some, if not all, state common law claims are preempted by the MDA, these courts have failed to devote any attention to the meaning of "general applicability" within the context of the MDA and its accompanying regulations. They have also failed to consider the question of whether Class III devices as a group can constitute a "*particular* device" within the FDA's understanding of that term. *See e.g., King,* 983 F.2d at 1139; *Stamps,* 984 F.2d at 1420-21; *Martello,* 42 F.3d at 1169. In addition, these courts have ignored the existence of other regulations promulgated by the FDA like § 808.1(d)(6)(ii) which specifically provides that a state or local requirement prohibiting the manufacture of adulterated or misbranded devices, a subject of the FDA premarket approval process, is not preempted unless it is interpreted or enforced by the state or local government in such a manner as to create a "substantive requirement for a *specific* device." 21 C.F.R. § 808.1(d)(6)(ii).

The reasoning of courts which have found that the premarket approval process preempts state law claims stands in sharp contrast to the analysis of Class II

devices. In Class II cases courts have consistently focussed both on the specificity of the federal requirement and the particularity of the device. For example, in *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246 (5th Cir.), *reh'g denied*, 873 F.2d 297 (1989), the court refused to preempt state laws relating to the design, construction, and composition of tampons because the only federal regulations applying to tampons, as a *particular* device, were labeling and warning requirements. *See also Anguiano v. E.I. DuPont de Nemours & Co.*, 44 F.3d 806, 810 (9th Cir. 1995) (holding that "[b]ecause the FDA ha[d] not promulgated specific regulations regarding [the product], the MDA [did] not preempt Anguiano's state law claims"). Thus, other courts have required less overall specificity under § 808.1(d) for Class III devices than for Class II devices. They have required particularity in the preemption analysis of Class II devices, but have ignored the word "particular" in the preemption analysis of Class III devices.

Such distinctions between Class II and Class III devices make little sense.[2] Congress enacted the MDA to

---

[2] Other courts have suggested that preemption is more applicable to Class III devices because the level of regulatory control is greater for Class III devices than for Class II devices. *See, e.g., Martello* 42 F.3d at 1168. While it is true that Class II devices are subject to specific performance standards only *if* the FDA deems them a sufficient health hazard whereas all Class III devices are subjected to a stringent "premarket approval process," this distinction in no way changes the fact that the MDA does not preempt claims based upon state common law of general applicability.

ensure that safe and effective medical devices were introduced into the market. H.R.Conf.Rep. No. 1090. There is no reason for a court's preemption analysis to change depending on the class of device in issue. In implementing the MDA, the FDA has explicitly interpreted § 360k(a) to exempt certain state laws which affect medical devices. As long as the FDA's interpretation of the MDA's preemption provision does not contravene congressional intent, the FDA's interpretation is controlling. *Chevron*, 467 U.S. at 844.

Section 808.1(d)(1) provides that the MDA does not preempt laws of general applicability. State common law is a law of general applicability. Although specific state common laws may have come into existence in response to a harm created by a particular device, state common law does not relate solely to or regulate any *particular* device or product to the exclusion of other devices or products. Courts which have found state common law actions to be preempted have generally relied on the Supreme Court plurality's conclusion in *Cipollone* that state common law can exert a regulatory effect on business. *Cipollone*, 112 S.Ct. at 2620 (citing *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)). *See e.g. Stamps*, 984 F.2d at 1422; *King*, 983 F.2d at 1134 (citing *San Diego Building Trades*).

However, the fact that state common law *may* have an indirect regulatory effect is not dispositive as to whether it qualifies as a *specific* requirement applicable to a *particular* device. Unlike positive state enactments, common law imposes only an indirect effect on manufacturers. Defendants in common law damages actions retain the

freedom to choose their own response to the legal challenges they face. For example, manufacturers facing common law challenges retain the discretion whether to alter their product or whether to bear the cost of any lawsuits that might result from their decision, whereas, manufacturers bound by positive state enactments are required to conform their product to the law. *See Cipollone*, 112 S.Ct. at 2627 (Blackmun, J., dissenting). The potential for state common law to create an indirect regulatory effect is insufficient to alter the fact that state common law is a law of general applicability and therefore cannot qualify as a *specific* requirement which may be preempted by the MDA.

In addition, it makes little sense to hold that the FDA's premarket approval process qualifies as a "*specific* requirement applicable to a *particular* device." 21 C.F.R. § 808.1(d) (emphasis added). *All* Class III devices are required to obtain premarket approval before being sold in interstate commerce. 21 U.S.C. § 360e; 21 C.F.R. § 814.1. The fact that the premarket approval process involves specific requirements, *see* 21 C.F.R. § 814, 820, must not be confused with the premarket approval requirement itself acting as a *specific* requirement. The result of holding that the premarket approval process is a "specific requirement applicable to a particular device" is the preemption of claims which, if barred, leave injured plaintiffs without any remedy in state or federal law. *See Michael*, 46 F.3d at 1320 (noting that the MDA does not oblige any Class III manufacturer or distributor to compensate a person injured by a Class III device for their medical expenses or their pain and suffering).

As the Supreme Court held in *Silkwood*, it is incredible to believe that Congress would, without comment, void all means of relief for those injured by illegal conduct. *Silkwood*, 464 U.S. at 251. State common law damages actions guarantee people who are injured by a manufacturer the opportunity to be compensated for their harm. State regulation of manufacturers directly governs their actions in releasing their goods into the market. Thus, state common law serves a different purpose than state regulation and is unlikely to have been the target of congressional attempts to promote the introduction of safe medical devices onto the market or even to curb dual regulation of the medical devices industry. Reading the MDA's preemption provision in the manner advocated by the defendant would result in consumers of Class III devices being left without recourse for any harm suffered. Such a result flies in the face of the congressional intent behind the MDA legislation: consumer protection. 43 Fed.Reg. 18,663 (May 2, 1978).

The federal law requiring the premarket approval of Class III devices was not enacted in order to free manufacturers from the everyday burdens of the marketplace after they are permitted to enter it. Premarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers. Courts which have held to the contrary have done so in contravention of the FDA's regulations and statements concerning the preemptive scope of the MDA. The FDA's determination that § 360k(a) must be read narrowly establishes a plausible interpretation of the statute and comports with the congressional intent behind the legislation. Absent a compelling reason to overturn the FDA's interpretation of the

legislation, we must adopt that interpretation and reverse the district court's grant of summary judgment.

REVERSED AND REMANDED.

REINHARDT, Circuit Judge, concurring:

I join fully in Judge Ferguson's opinion for the court. I write separately to clarify further the meaning of the word "requirement" as it is used in 21 U.S.C. § 360k(a). The Medical Device Amendments of 1976 (the "MDA") preemption provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any *requirement* –
>
> (1) which is different from, or in addition to, any *requirement* applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a *requirement* applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The first reference to "requirement" is to requirements imposed by states or local entities, while the second and third references are to federal requirements imposed under the MDA. It is the meaning of the first "requirement" – state or local requirements applicable to medical devices – that is at issue here.[1]

---

[1] The Eleventh Circuit erroneously suggests that this court understands the first reference to "requirement" to include general state tort law. *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 (11th Cir. 1995). The *Lohr* court's suggestion is based

Some courts have concluded that the term "requirement" as it relates to state or local regulation includes state common law of general applicability. These courts have either accepted that view without explanation, relied on a proposition endorsed in a different context by only a plurality of the Supreme Court in *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608 (1992), or read 21 C.F.R. § 808.1(b) in isolation from the rest of § 808.1.[2] As discussed in Judge Ferguson's opinion for the court, the

---

on dicta in *Anguiano v. E.I. Du Pont De Nemours & Co.*, 44 F.3d 806, 809 (9th Cir. 1995). In *Anguiano*, we actually considered the second and third references to "requirement" (the federal references) in § 306k(a), and held that the plaintiffs' state claims were not preempted. We concluded that the *federal* controls applicable to the Class II device in question were too insubstantial to constitute a "requirement" under the MDA. *Id.* at 810. Class III devices were not at issue in that case and our speculation as to how Class III devices might be treated under the statute was just that – speculation. So, too, were any observations regarding the scope or preemptive effect of the *first* reference to "requirement," the requirement at issue here.

[2] *See, e.g., Gile v. Optical Radiation Corp.*, 22 F.2d 540, 542 (3rd Cir.), *cert. denied*, 115 S.Ct. 429 (1994) (declaring that the Supreme Court has clearly stated that the word "requirement," in the context of an express preemption provision, includes state law claims); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir.), *cert. denied*, 113 S.Ct. 327 (1992) (suggesting in dicta that § 360k(a) preempts state common law decisions); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1168 (8th Cir. 1994), *cert. denied*, 115 S.Ct. 2614 (1995) (relying on phrase "whether established by statute, ordinance, regulation, or court decision" in 21 C.F.R. § 808.1(b) to conclude preemption extends to state tort actions); *Lohr*, 56 F.3d at 1342 (adopting the Seventh Circuit's reasoning and relying on the conclusions of other circuits that common law actions are state requirements within the meaning of § 360k(a)).

dicta and occasional holdings of the courts that have concluded that the MDA preempts state common law ignore the controlling interpretation of § 360k(a) adopted by the FDA, the federal agency charged with implementing the Medical Device Amendments.

The term "requirement" is not self-defining, and Congress did not provide any definition of the term as it is used in relation to the actions of a state (the first reference) or in relation to federal actions (the second and third references). Rather, Congress left to the FDA the task of adopting implementing regulations defining "requirement," and explaining the operation of other provisions of the MDA. The controlling interpretations of the term "requirement" are found in 21 C.F.R. § 808.1. Read in its entirety, section 808.1 clearly provides that § 306k(a) preempts only state and local requirements the terms of which are *specifically* "applicable to medical devices," and that it does *not* preempt state and local requirements "of general applicability;" i.e., state and local requirements the purpose of which relates "to other products in addition to [medical] devices." 21 C.F.R. § 808.1(a); 21 C.F.R. § 808.1(d)(1). In other words, the FDA's implementing regulations define and limit the term (state) "requirement." Under those regulations, what is preempted by the MDA are state and local *medical device* requirements, not state and local general laws, whether tort or contract, common or statutory. 21 C.F.R. § 808.1(d)(1). In short, § 808.1 makes it clear that general state tort law is *not* preempted by the MDA.

A few courts have pointed to the inclusion of the term "court decisions" in 21 C.F.R. § 808.1(b) as evidence that state tort law claims are generally preempted. *See,*

e.g., Gile v. Optical Radiation Corp., 22 F.3d 540, 544 n.3 (3rd Cir.), *cert. denied*, 115 S.Ct. 429 (1994). They argue that the inclusion of "court decisions" demonstrates that all state common law is preempted. The argument is a non sequitur. The court decisions that are preempted are only those that involve state requirements of specific rather than general applicability. The fact that a court decision involves a medical device is not determinative of whether that court decision constitutes a preempted state requirement; what is determinative is whether the court decision implements a principle of general tort law or is based on a rule or regulation aimed specifically at medical devices. A contrary interpretation would bring § 808.1(b) into direct conflict with § 808.1(d)(1). There is no reason for such a conflict, since the two provisions, read in context, can easily be reconciled.[3]

---

[3] Appellate courts have generally ignored 21 C.F.R. § 808.1(d)(1). Only a few circuit courts even bother to mention the subsection. *See Michael v. Shiley, Inc.*, 46 F.3d 1316, 1323 n.4 (3rd Cir. 1995) (noting plaintiff's argument based on the "general applicability" language in § 808.1(d)(1) but expressing no view on the effect of § 808.1(d)(1) "because Shiley disclaimed all implied warranties as it was entitled to do under the Code"); *Gile*, 22 F.3d at 543 n.2 (ignoring the "general applicability" language and seemingly relying on the fact that neither the phrases "state tort claim" nor "common law claim" are listed in 21 C.F.R. § 808.1(d)); *King v. Collagen Corp.*, 983 F.2d 1130, 1139 (1st Cir.), *cert. denied*, 114 S.Ct. 84 (1993) (Aldrich, J., concurring) (offering the proposition that "When a statute is clear the agency interpretation must give way" as explanation for why § 808.1(d)(1) does not conflict with the court's decision). District courts have addressed § 808.1(d)(1) more often than appellate courts with varied conclusions. *Compare Mitchell v. Collagen Corp.*, 870 F.Supp. 885 (N.D. Ind. 1994) (rejecting plaintiffs contention, based upon § 808.1(d), "that state tort laws of

Section 808.1(b) sets forth the "general rule" that states may not establish or maintain "requirements" with respect to medical devices that differ from the federal rules governing these devices. As noted *supra*, the term "requirement" is defined as including "court decisions." We can assume for purposes of this decision that were we to read § 808.1(b) in isolation, there might be some ambiguity with respect to the latter term, and that it could be read to refer either to all court decisions or only to those court decisions that adopt special rules applicable to medical devices. However, when read together with § 808.1(d)(1), any ambiguity disappears.

In § 808.1(d)(1), which, of course, appears *after* § 808.1(b), the scope of the earlier section is expressly clarified and limited. Section 808.1(d)(1) specifically provides that "requirements" involving laws of general applicability, are *not* preempted. Since, under § 808.1(b), "requirements" includes "court decisions," "court decisions" must be read as *not* including decisions involving rules of general applicability. Any other reading would make the scope of the term "court decisions" far broader than, and entirely inconsistent with, the other terms (i.e. statute, ordinance, and regulation) which are included within the definition of "requirement." In short, the inclusion of the term "court decision" in § 808.1(b) cannot

---

general applicability (i.e., not applicable only to medical devices) are not preempted") with *Ministry of Health v. Shiley*, 858 F.Supp. 1426, 1435 (C.D. Cal. 1994) (relying on the "general applicability" language of § 808.1(d)(1) and Advisory Opinions issued by the Office of the Chief Counsel for the FDA to conclude state tort claims are not subject to blanket preemption).

serve to modify the provision in § 808.1(d) that limits the term "requirements" to those provisions applicable expressly to medical devices. If for no other reason than the order in which they appear, it is § 808.1(d) that specifically limits and explains the scope of the term "court decision," as used in § 808.1(b), not vice-versa.

To summarize, if a state common law requirement is not specifically directed at medical devices, but affects such devices in the same manner as it affects all other products, a claim based upon that state law requirement is not preempted. Accordingly, generally applicable state common law, including tort law, is not preempted by § 360k(a).

APPENDIX D

[Filed Jan. 18, 1994]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. C89-2331-CAL

CHARLOTTE KENNEDY, *et al.*,

Plaintiffs,

v.

COLLAGEN CORPORATION,

Defendant.

ORDER GRANTING MOTION FOR SUMMARY JUDGMENT

Defendant Collagen Corporation's motion for summary judgment came on for regularly noticed hearing on December 17, 1993, the Honorable Charles A. Legge, District Judge, presiding. Kathleen D. Patterson of Sedgwick, Detert, Moran & Arnold, and Joe W. Redden, Jr., of Beck, Redden & Secrest, appeared as counsel on behalf of defendant, Collagen Corporation. Michael M. Essmyer, of Michael M. Essmyer & Associates, appeared on behalf of plaintiffs, Charlotte Kennedy and Robert Kennedy.

After full consideration of the evidence and points and authorities submitted by the parties, and oral arguments of counsel, it appears and the Court finds, for the reasons set forth by the Court on the record in open court, which record is hereby incorporated by reference, that plaintiffs' claims are preempted under 21 U.S.C.

section 360k(a), that there is no genuine issue of material fact with respect thereto and, therefore, Collagen Corporation is entitled to judgment as a matter of law.

IT IS ORDERED THAT Collagen Corporation's motion for summary judgment is granted and judgment shall be ordered forthwith as requested in said motion in favor of Collagen Corporation and against Charlotte Kennedy and Robert Kennedy.

Dated: January 18, 1994

/s/ Charles A. Legge
CHARLES A. LEGGE
United States District Judge

APPENDIX E

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 91-15597

D.C. No. CV-89-02331-CAL

CHARLOTTE KENNEDY and ROBERT KENNEDY,

Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of California
Charles A. Legge, District Judge, Presiding

Argued and Submitted May 15, 1992
San Francisco, California

MEMORANDUM*

(Filed Sept. 8, 1992)

BEFORE: FERGUSON, REINHARDT and KOZINSKI, Circuit Judges.

This is a products liability case which ended with the granting of summary judgment for the defendant. We reverse.

---

* This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by 9th Cir. R. 36-3.

The action arises from Charlotte Kennedy's treatment with Zyderm[R] Collagen Implant ("Zyderm"), a prescription medical product manufactured by defendant Collagen Corporation ("Collagen"). Zyderm is injected by a doctor into facial wrinkles for a smoother appearance. Kennedy claims to have developed systemic lupus erythematosus, an automimmune [sic] disease, as a result of this treatment.

Collagen filed a motion for summary judgment on the ground that the plaintiffs had failed to produce any evidence establishing a prima facie case of causation.

At the hearing on the motion, the plaintiffs submitted an affidavit executed by Dr. Joseph Spindler on the issue of causation. The district court concluded that neither the testimony of the plaintiffs' designated expert witnesses nor Dr. Spindler's affidavit raised a genuine issue of material fact on the issue of causation. In addition, the court denied the plaintiffs' motion to designate additional experts, including Dr. Spindler, because the motion was untimely.

The plaintiffs subsequently filed a motion for a new trial, which the court also denied.

We reverse. Dr. Spindler's affidavit established the existence of a genuine issue of material fact regarding causation and was sufficient to preclude summary judgment.

DISCUSSION

We review the district court's grant of summary judgment de novo. *State Farm Fire & Casualty Co. v. Martin*, 872

F.2d 319, 320 (9th Cir. 1989). We must determine, viewing the evidence in the light most favorable to the nonmoving party, whether there are any genuine issues of material fact and whether the district court correctly applied the relevant substantive law. *Tzung v. State Farm Fire & Casualty Co.*, 873 F.2d 1338, 1339-40 (9th Cir. 1989).

In moving for summary judgment, the defendant did not offer any testimony or affidavits of its own witnesses. Instead, it relied on the deposition testimony of the plaintiffs' experts, excluding of course Dr. Spindler's affidavit.

We confine our study of the record to Dr. Spindler's affidavit and do not determine the sufficiency of the deposition testimony of the plaintiffs' other medical experts.

Under California law, the Kennedys were required to prove causation "within a reasonable medical probability based upon competent expert testimony." *Jones v. Ortho Pharmaceutical Corp.*, 163 Cal. App. 3d 396, 402 (1985). Dr. Spindler's affidavit was such testimony and was sufficient to establish the existence of a genuine issue of material fact regarding causation. Dr. Spindler affirmed that "[b]ased on reasonable medical probability," the Zyderm injections caused Charlotte Kennedy's systemic immunological injuries. Dr. Spindler based his opinion on his examination of Kennedy; review of her medical history and records; numerous laboratory tests of Kennedy which showed a positive ANA, anti-histone antibody, and anticentromere antibody; and the temporal relationship between the injections and her condition. Accepted on its own terms, the affidavit demonstrated a "reasonable

medical probability" that the defendant's conduct caused Kennedy's injuries.

The defendant contends that Dr. Spindler's use of language such as "suspect" and "could have been" rendered the affidavit insufficient to establish a "reasonable medical probability." We disagree.

California courts have held that words such as "speculative" and "conjecture" do not render a doctor's testimony speculative if, taken as a whole, the testimony states the doctor's opinion of reasonable medical probability. *See Cullum v. Seifer*, 1 Cal. App. 3d 20, 26 (1969); *Gay v. Workers' Compensation Appeals Bd.*, 96 Cal. App. 3d 555, 564 (1979). In *Gay*, the plaintiff appealed a finding of the Workers' Compensation Appeals Board that apportioned 50 percent of his psychiatric disability as nonindustrial. The plaintiff attacked the opinion of the psychiatrist who had recommended apportionment and argued, *inter alia*, that the opinion could not support apportionment because it included the statement, "Whether any of the symptoms preexisted [the patient's] current employment is speculative since the patient denies it." The plaintiff contended that this statement showed that the psychiatrist was improperly "speculating" about apportionment. The court disagreed, stating:

> In evaluating a medical report, isolated statements may be misleading. Intellectual candor of a physician may lead to single statements which, when isolated, may be misunderstood. In evaluating the evidentiary value of medical evidence, a physician's report and testimony must be considered as a whole rather than in segregated parts. Thus, the physician's entire report

> and testimony when considered a [sic] a whole, must demonstrate that, based upon reasonable medical probability, there is a legal basis for apportionment.

96 Cal. App. 3d at 564 (citations omitted).

In *Cullum*, a malpractice case, the court reviewed the testimony of an expert witness, a doctor, who testified on the issue of proximate cause. The court examined the totality of the doctor's testimony on the issue and concluded that even though the witness referred at one point to "conjecture," the testimony as a whole stated the doctor's opinion of reasonable medical probability. The court explained:

> The isolated characterization of 'conjecture' must be weighed as to its true meaning and significance in the light of the testimony which preceded it. . . . [T]he main object is not to draw fine distinctions based upon accurate definitions or words, but to ascertain the real idea expressed."

1 Cal. App. 3d at 26 (citations and internal quotation marks omitted). Here, Dr. Spindler's affidavit, read in its entirety, clearly stated his opinion of reasonable medical probability.

A jury was entitled to hear Dr. Spindler's testimony. *See Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1535 (D.C. Cir. 1984), *cert. denied*, 469 U.S. 1062 (1984). In *Ferebee*, where both sides presented expert opinion testimony on the issue of whether paraquat poisoning caused the plaintiff's pulmonary fibrosis, the D.C. Circuit held that the jury was entitled to decide the victor in the battle of experts. *Id.* The court distinguished between the standard

for the admission of evidence based on novel scientific techniques or methodologies, where "the basis of that opinion must be shown to be generally accepted as reliable within the expert's particular scientific field," and the standard for "the admission of scientific opinion testimony that, while controversial in its conclusions, is based on well-founded methodologies." *Id.* (citations and internal quotation marks omitted). The court stated further:

> [A] cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, such as use of tissue samples, standard tests, and patient examination, products liability law does not preclude recovery until a "statistically significant number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical. In a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal sufficiency; if reasonable jurors *could* conclude from the expert testimony that paraquat more likely than not caused [the plaintiff's] injury, the fact that another jury might reach the opposite conclusion or that science would require more evidence before conclusively considering the causation question resolved is irrelevant. That [the plaintiff's] case may have been the first of its exact type, or that his doctors may have been the first alert enough to recognize such a case, does not mean that the testimony of those doctors, who are concededly

> well qualified in their fields, should not have been admitted.

Id. at 1535-36 (emphasis in original).

Here, the reliability of Dr. Spindler's methodology is not disputed. The district court was inaccurate in believing that Dr. Spindler's opinion was based primarily on the temporal relationship between the Zyderm injections and Kennedy's injuries and was not based on "any other laboratory tests of plaintiff, epidemiological evidence, or toxicological evidence." Furthermore, the court was not presented with any facts demonstrating that Dr. Spindler's methodology differed from procedures generally accepted by authorities in the field of immunology.[1] "[I]n determining . . . whether the informational basis of an expert opinion is of a type reasonably relied upon by experts in the field, "[t]he proper inquiry is not what the court deems reliable, but what experts in the relevant discipline deem it to be." *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829, 853 (3rd Cir. 1990), *cert. denied*, 111 S.Ct. 1584 (1991) (citations omitted).[2] *See also id.* at 856-58;

---

[1] Nor did Collagen contend that Dr. Spindler was not a competent medical expert.

[2] In *Paoli*, the Third Circuit reversed the district court's grant of summary judgment for defendants and held that the district court had failed to give reasons for excluding as unreliable the bulk of the expert testimony upon which the plaintiffs had relied to establish causation.

In the present case, it is unclear whether the district court found Dr. Spindler's affidavit inadmissible under Fed. R. Evid. 703, or whether the court found the affidavit admissible but concluded that the evidence was nonetheless insufficient to enable a jury to find causation. We need not resolve this

DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941 (3rd Cir. 1990) (reversing district court's grant of summary judgment for defendants; holding that the district court erred in failing to make a record-supported, factual finding that plaintiff's doctor relied upon data not regarded as reliable by experts in the field). Thus, the district court erred in concluding that Dr. Spindler's affidavit was insufficient to preclude summary judgment.

In closing, we note that *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128 (9th Cir. 1991), and other Bendectin cases are distinguishable. In holding that the plaintiffs' evidence was unreliable, we and other circuits relied on specific factual findings as to what constituted generally accepted scientific methodology. *Id.* at 1130-31. *See also Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 311-13 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990); *DeLuca*, 911 F.2d at 949-52 (discussing Bendectin case law from other circuits). In *Daubert*, we upheld summary judgment based on the large volume of unfavorable epidemiological studies establishing the absence of causation. 951 F.2d at 1129. *See also Brock*, 874 F.2d at 311. In that case, "[p]laintiffs' evidence of causation consisted primarily of expert opinion based on *in vitro* and *in vivo* animal tests, chemical structure analyses and the reanalysis of epidemiological studies." The defendant's evidence included "the affidavit of a physician and

---

ambiguity, however, because we conclude that the affidavit, taken on its own terms, established causation within a reasonable medical probability.

epidemiologist who reviewed all of the available literature on the subject, which included more than 30 published studies involving over 130,000 patients, and concluded that no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects." *Daubert*, 951 F.2d at 1129. Here, Collagen presented no facts contradicting Dr. Spindler's testimony.

We hold:

1. The order granting the defendant's motion for summary judgment is reversed.

2. The order denying a new trial is mooted.

3. The order denying the plaintiffs leave to designate additional experts is vacated for reconsideration in light of the reversal of summary judgment.

REVERSED AND REMANDED.

Kennedy v. Collagen Corporation, No. 91-15597

KOZINSKI, Circuit Judge, dissenting:

This is the heart of Dr. Spindler's affidavit:

> The existence of anti-histone antibody is *suspect* [sic] that her immune system was triggered by an external source, which *could have been* the bovine collagen injections in her case. . . .
>
> Mrs. Kennedy's medical history, records and current laboratory results are *consistent with a temporal relationship* between her injections and her medical condition, including a severe adverse reaction to

> Defendant's product, with systemic immune disorders and deteriorating medical condition and clinical symptoms.

ER, Tab D, at 17 (emphasis added). Dr. Spindler also adds that "[m]ore recently, I have obtained and evaluated current laboratory rests [sic] results for her, which reveal a change in her ANA, and in the existence of anti-centromere antibody, previously not present." *Id.* Nowhere does Dr. Spindler explain the meaning of "ANA" or "anticentromere antibody," nor does he intimate what either of these has to do with plaintiff's case against the defendant.

Dr. Spindler's affidavit is simply too indefinite to establish a "reasonable medical probability" that Kennedy's disorder is in any way linked with defendant's collagen treatments; it is rank speculation. Under the substantive law of California, which we are bound to apply, Kennedy was obligated to put forth "a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Kennedy's reliance upon this affidavit was insufficient to carry her summary judgment burden. I would therefore affirm the judgment against her.

APPENDIX F

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

No. 91-15597

D.C. No. CV-89-02331-CAL

CHARLOTTE KENNEDY; ROBERT L. KENNEDY,

Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of California
Charles A. Legge, District Judge, Presiding

Argued and Submitted May 15, 1992
San Francisco, California

MEMORANDUM*

(Filed JUN 8 1992)

Before: FERGUSON, REINHARDT and KOZINSKI, Circuit Judges.

The district court did not err in ruling that Kennedy had failed to present sufficient evidence of causation to

---

* This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by 9th Cir. R. 36-3.

survive summary judgment. Under California law, Kennedy was required to prove causation "within a reasonable medical probability." *Jones v. Ortho Pharmaceutical Corp.*, 163 Cal. App. 3d 396, 402 (1985). Her expert affidavits on causation, however, were either speculative, highly equivocal, or both. They thus provided an insufficient basis for a reasonable jury to find causation. *See id.* at 402-04; *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-24 (1986).

The district court's denial of Kennedy's motion for a new trial based on newly discovered evidence was not an abuse of discretion; Kennedy failed to show that she had exercised due diligence in searching for, but not discovering, the evidence earlier. *Contempo Metal Furniture Co. v. East Texas Motor Freight Lines, Inc.*, 661 F.2d 761, 766 (9th Cir. 1981).

Kennedy's challenge to the district court's refusal to designate Dr. Spindler as an expert for trial is moot, as there will be no trial.

AFFIRMED.

APPENDIX G

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. C-89-2331-CAL

CHARLOTTE KENNEDY, *et al.*,

Plaintiffs,

v.

COLLAGEN CORPORATION,

Defendant.

ORDER ON MOTION FOR SUMMARY JUDGMENT

(Filed Dec. 10, 1990)

This is a product liability action, for injuries allegedly resulting to plaintiff Charlotte Kennedy from the use of defendant's product Zyderm Collagen Implant (ZCI). Mrs. Kennedy was treated with ZCI in 1982 as a cosmetic aid. By 1983 she developed systemic lupus erythematosus (SLE). She alleges that the SLE condition was caused by the ZCI. Her husband joins as a plaintiff, alleging loss of cosortium.

I.

Defendant has moved for summary judgment, contending that there is no genuine issue of fact that palintiff's [sic] SLE was caused by ZCI. As discussed below,

defendant's motion is accompanied by evidence demonstrating the lack of causal medical connection between ZCI and SLE.

Plaintiffs have opposed the motion, and their opposition includes a request for a continuance of the motion under Rule 56(f) of the Federal Rules of Civil Procedure. Their opposition and request for continuance primarily concern the late offer by plaintiffs of evidence from Dr. Joseph Spindler. This court received Dr. Spindler's affidavit at the oral argument of the summary judgment motion. Plaintiffs also request leave of the court to designate Dr. Spindler as an additional expert witness for trial, since expert designations were concluded in October 1989.

II.

The primary issue in this case, and this motion, is medical causation. However, because of plaintiff's request for a continuance, the late filing of Dr. Spindler's affidavit, and the request to designate Dr. Spindler as an additional expert for trial, it is necessary to review the procedural history of the case.

The action was originally filed in February 1988, and was assigned to another judge of this court. When the case was reassigned to the undersigned judge, a status conference was held on August 11, 1989. At the status conference, the court was advised that all discovery had been concluded, except discovery regarding experts. This court then set the following deadlines: designation of experts by October 1989, a discovery cutoff of November 1989, and trial in early 1990. On September 15, 1989, on

plaintiffs' motion, this court compelled that certain of defendant's medical files be produced to plaintiffs. In December 1989, plaintiffs' counsel withdrew from the case, and the trial date was therefore vacated. Several status conferences were held from January 1990 through May 1990 to allow plaintiffs time to obtain new counsel and for new counsel to become familiar with the case. New counsel appeared in May 1990. A scheduling and status conference was held in June, 1990, at which time the court set the trial date for early 1991.

Defendant filed this motion for summary judgment in October 1990, and the hearing was held on November 16, 1990. The motion was then submitted for decision. The court has reviewed the moving and opposing papers, the record of the case, some subsequent communications sent to the court by plaintiffs and defendant, and the applicable legal authorities. The court concludes that plaintiffs' request for further accommodation must be denied, and summary judgment must be granted in favor of defendant.

III.

As stated, defendant contends that there is no genuine issue of material fact regarding the absence of causation between SLE and ZCI.

Plaintiffs' substantive claims are governed by California law. Under California law, in order to establish a prima facie case of product liability, plaintiffs must present sufficient evidence on the issue of medical causation. *Jones v. Ortho Pharmaceutical Corporation*, 209 Cal. Reptr. 456, 460 (1985): "The law is well settled that in a personal

injury action causation must be proven within a reasonable medical probability based upon competent medical testimony. Mere possibility alone is insufficient to establish a prima facie case . . . "

Defendant's motion for summary judgment squarely raises the issue of whether a causal connection between ZCI and SLE can be demonstrated by plaintiffs within a reasonable medical probability and based upon competent medical testimony. The motion is accompanied by extracts from the depositions of physicians, previously designated as experts in this case. That testimony need not be discussed in detail. Suffice it to say that the motion and the testimony establish a prima facie case of the absence of medical causation.

IV.

Under the *Celotex* trilogy, *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986); *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242 (1986), the burden then shifts to plaintiffs to raise a genuine issue of material fact on causation. Plaintiffs' written opposition to the motion, filed before the question of Dr. Spindler's affidavit arose, was based upon the testimony of their designated expert Dr. Tuffanelli. However, his testimony is equivocal. He stated, "so in my mind, until I see some good honest published data in that area, I will remain *unconvinced* that it (ZCI) is *not* causing these diseases (SLE)." Even that equivocal opinion was undercut by testimony from his deposition. He stressed that a causal connection was merely "possible." He testified that no scientific data

exists that examine the incidents of autoimmune diseases in persons who have used ZCI, and that it would therefore be difficult for any expert to base an opinion on information reasonably relied upon by any expert in the field. He did not express an opinion on the probability of causation, and he indicated that causation theories are currently based upon speculation. This is not be evidence [sic] sufficient to meet the standard of Federal Rule of Evidence 703, and does not meet the standard of proof of medical causation required by California law. *Jones*, 209 Cal. Rptr. at 461.

Plaintiffs offered the affidavit of Dr. Spindler at the oral argument. And the court has reviewed and considered that affidavit. However, the court concludes that even Dr. Spindler's affidavit does not sustain plaintiffs' burden of establishing a genuine issue of material fact on causation. His opinion is based primarily on the temporal relationship between plaintiffs' use of ZCI and the development of her disease (*post hoc, ergo propter hoc*). The most that he can say is the the ZCI injections were "suspect," and that her condition "could have been" caused by taking ZCI. There do not appear to be any other laboratory tests of plaintiff, epidemiological evidence, or toxicological evidence upon which the opinion is based. Therefore, the court must conclude that even Dr. Spindler's affidavit does not create the genuine issue of material fact on medical causation necessary to defeat summary judgment.

V.

Plaintiffs seek leave to designate further experts, primarily Dr. Spindler, and to continue consideration of the motion for summary judgment. This request must be denied.

As the history of the case demonstrates, experts were designated over a year ago in October, 1989. And this court was generous to plaintiffs in staying and continuing the proceedings from December 1989 to May 1990, when plaintiffs' new attorney entered the case. The change of counsel might arguably be a ground for granting plaintiffs further accommodation to designate new experts. However, no attempt to designate other experts was made between the date that plaintiffs' new counsel entered the case in May of this year and the date of the oral argument of the summary judgment motion.

IT IS THEREFORE ORDERED that summary judgment be granted in favor of defendant and against plaintiffs.

Dated: December 10, 1990.

/s/ Charles A. Legge
CHARLES A. LEGGE
United States District Judge

APPENDIX H

[Filed Jan. 16, 1996]

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 91-15197

D.C. No. CV-89-02331-CAL

CHARLOTTE KENNEDY and ROBERT I. KENNEDY,

Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,

Defendant-Appellee.

ORDER

Before: FERGUSON, REINHARDT, and THOMPSON, Circuit Judges.

The panel as constituted in the above case has voted unanimously to deny the petition for rehearing. Judges Reinhardt and Thompson voted to reject the suggestion for a rehearing en banc and Judge Ferguson recommended the denial of the en banc request.

The full court has been advised of the suggestion for en banc hearing and no judge of the court has requested a vote on the suggestion for rehearing en banc. Fed. R. App. P. 35.

The petition for rehearing is denied and the suggestion for a rehearing en banc is rejected.

Supreme Court, U.S.
FILED
MAR 30 1999
OFFICE OF THE CLERK

No. 98-1424

In The

Supreme Court of the United States

October Term, 1998

COLLAGEN CORPORATION,

Petitioner,

v.

CHARLOTTE KENNEDY and ROBERT KENNEDY,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

RESPONDENTS' BRIEF IN OPPOSITION

MICHAEL M. ESSMYER
Counsel of Record
ESSMYER & TRITICO, L.L.P.
4300 Scotland
Houston, Texas 77007
(713) 868-1111

SUSAN A. ALLINGER
4300 Scotland
Houston, Texas 77007
(713) 868-1111

Counsel for Respondents

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

1098

QUESTION PRESENTED

Whether the Ninth Circuit Court of Appeals correctly reversed the trial court's granting of summary judgment below due to its abuse of discretion in excluding certain expert witness testimony under an inflexible application of *Daubert*.

TABLE OF CONTENTS

Page

Question Presented i

Table of Authorities iii

Opinions Below 1

Statement of the Case 1

Reasons Why the Petition Should Be Denied 3

1. The Ninth Circuit's opinion is consistent with the Court's decisions in *Daubert* and *Kumho*, and no conflict is shown 3

2. Neither the decision below nor the record raises the issue of "independent validation," and the issue is not properly before this Court 4

3. The Ninth Circuit did not hold that petitioner had the burden of proving unreliability of the expert's methodology 5

4. This Court refused to review petitioner's state law arguments in 1993, and the issue is moot .. 6

Conclusion 7

TABLE OF AUTHORITIES

Page

CASES

Ambrosini v. Labarraque, 101 F.3d 12 (D.C. Cir. 1996), *cert. dismissed, Upjohn v. Ambrosini*, ___U.S.___, 117 S.Ct. 1572 (1997) 5

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) 2, 3, 4

Delta Airlines v. August, 450 U.S. 346 (1981) 5

Kumho Tire Co. v. Carmichael, ___U.S.___, No. 97-1709 (March 23, 1999) 3, 4

RULE

Supreme Court Rule 14.1(a) 1

OPINIONS BELOW

Respondents Charlotte and Robert Kennedy disagree with petitioner Collagen Corporation's inclusion of prior rulings and appeals of this case from 1990 through 1995 in Collagen Corporation's petition. The lengthy history and prior appeals in this case have no bearing on Collagen Corporation's petition and present nothing for review by this Court.

The only relevant and viable ruling before this Court is the Ninth Circuit's ruling of December 7, 1998.

STATEMENT OF THE CASE

Respondents respectfully request that this Court deny the petition for writ of certiorari filed by petitioner, which seeks review of the Ninth Circuit's opinion below. The Ninth Circuit Court of Appeals opinion appears at 161 F.3d 1226.

At the onset, respondents would note that the petition contains improper form and content and should not be considered by the Court; specifically:

(a) The "Questions Presented" portion violates Supreme Court Rule 14.1(a) in that it is argumentative, repetitious and unnecessarily detailed.

(b) The "Statement of the Case" contains extraneous and argumentative discussions of the two prior appeals of this case, neither of which has any bearing on this petition and both of which were appealed to this Court and denied. Petitioner raises particularly lengthy arguments regarding the Ninth Circuit's 1992 ruling in this

case, the review of which was denied by this Court on June 28, 1993 under No. 92-1505. The Court has no jurisdiction to re-review such ruling, and it should not have been made a part of this petition.

(c) The "Statement of the Case" improperly argues the law, facts and rulings below to a degree where correction by respondents would be unreasonably cumbersome for the Court. Respondents instead state that Charlotte and Robert Kennedy filed suit against Collagen Corporation seeking damages for injuries caused by petitioner's product. Petitioner filed for summary judgment, alleging that the testimony of expert witness Joseph Spindler, M.D., was inadmissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The trial court agreed, granted summary judgment and dismissed the case. The Ninth Circuit reversed, and ruled that the trial court abused its discretion in failing to consider relevant scientific evidence relied on by Dr. Spindler to support his opinions. In holding that the reliability of Dr. Spindler's methodology was supported by "objective, verifiable evidence that the testimony [wa]s based on scientifically valid principles," the Ninth Circuit enumerated the objective, verifiable evidence he relied upon and the reliable methodology he applied, utilizing *Daubert* and the federal rules of evidence.

REASONS WHY THE PETITION SHOULD BE DENIED

1. The Ninth Circuit's opinion is consistent with the Court's decisions in *Daubert* and *Kumho*, and no conflict is shown.

Petitioner's complaints are two-fold: first, that the lower courts failed to require "independent validation" of the expert testimony in addition to "objective verification", and second, that the appellate court incorrectly applied the facts to the law. Neither complaint gives rise to a need for review by this Court.

In an apparent effort to distinguish the legal holding in this case from that of *Daubert*, petitioner fashions a specious argument that "independent validation" of an expert's methodology is a wholly-different criterion than the "objective verification" required by *Daubert*. Petitioner, disagreeing with the Ninth Circuit's reference to numerous factors giving rise to objective verification of the reliability of Dr. Spindler's methodology, argues that respondents failed to additionally provide independent validation of Dr. Spindler's methodology.

Petitioner fails to cite any source for "independent validation" as being a separate factor above and beyond "objective verification." Respondents contend that they are one and the same. The cases cited by petitioner at footnotes 5 and 6, page 24, reflect requirements of "objective, independent" validation or verification of the witnesses's methodology; nothing supports a position that these are two separate and exclusive criteria.

Nor does the Court's most recent *Daubert*-related decision in *Kumho Tire Co. v. Carmichael*, ___U.S.___, No.

97-1709 (March 23, 1999), require a specific finding of "independent validation" by the trial court in addition to "objective verification" of the reliability of expert witness methodology. Simply put, there is no such requirement and no conflict among the circuits regarding such non-existent issue.

The Ninth Circuit, as per *Daubert*, cited ample evidence of "objective verification" regarding Dr. Spindler's testimony. The decision below turns upon its own facts and does not present any legal issue of significance or conflict, and would have little, if any, significance for other litigants or courts.

The Ninth Circuit's ruling of December 7, 1998 carefully followed this Court's opinion in *Daubert* in both spirit and letter of the law, and should not be disturbed. It is also wholly consistent with *Kumho*, and in fact, adheres to this Court's admonitions that the *Daubert* factors are not exclusive and that a flexible approach must be used, taking into account the expert's particular knowledge and discipline, which the trial court here failed to do.[1] *Kumho*. The petition is without merit, and should be denied.

2. Neither the decision below nor the record raises the issue of "independent validation," and the issue is not properly before this Court.

Regardless, petitioner's argument that "independent validation" must be shown in addition to "objective

---

[1] To the extent that petitioner argues that Dr. Spindler's testimony was required to follow *Daubert*'s enumerated "laundry list" of specific factors, this argument was rejected by *Kumho*.

verification" of the methodology in question must fail, as this was never argued below and was not ruled on. The petition contains arguments not presented to the trial court or court of appeals, and is not before the Court. *Delta Airlines v. August*, 450 U.S. 346, 362 (1981) ("question presented in petition but not raised in court of appeals is not properly before us").

The petition is without merit and should be denied.

3. The Ninth Circuit did not hold that petitioner had the burden of proving unreliability of the expert's methodology.

Petitioner misconstrues the opinion below, if not simply misreads it. Nothing in the Ninth Circuit's decision states or suggests that it was petitioner's burden to prove that Dr. Spindler's methodology was unreliable. The sentence quoted by petitioner at page 26 of its petition simply notes that petitioner did not present any evidence *disputing* the reliability of Dr. Spindler's methodology. This is underscored by the Ninth Circuit's immediately-following reference to *Ambrosini v. Labarraque*, 101 F.3d 12 (D.C. Cir. 1996), *cert. dismissed*, ___U.S.___, 117 S.Ct. 1572 (1997), as "noting that lack of contradictory evidence supported admissibility of expert's opinion regarding causation." This was an evidentiary issue, not a burden of proof issue.

The court of appeals correctly placed the burden of proof on respondents, and no conflict or inconsistency exists. The petition is without merit and should be denied.

4. This Court refused to review petitioner's state law arguments in 1993, and the issue is moot.

Petitioner's allegations of insufficiency of Dr. Spindler's opinion on medical causation under California state law was rejected by the Ninth Circuit in 1992. *Collagen Corporation v. Kennedy*, No. 91-15597, unpublished opinion dated September 8, 1992, appearing as Appendix E to the Petition for Writ of Certiorari. Collagen Corporation appealed this ruling to the U.S. Supreme Court under Petition No. 92-1505, which was denied by the Court on June 28, 1993.

The Ninth Circuit ruled in 1992 that Dr. Spindler's testimony was sufficient under California state law to establish medical causation; the Ninth Circuit's 1998 ruling did not change or address such issue and cannot be argued as establishing a standard different from state law. As a result, the basis for petitioner's complaints regarding state law has already been presented to this Court and denied by prior petition, a controlling fact which petitioner failed to disclose to the Court in its petition.[2]

The Court has no jurisdiction to re-review its 1993 decision, and the issue is moot. The Ninth Circuit's current ruling below does not modify or discuss such state law issue anew, and nothing is presented for review.

The petition is without merit and should be denied.

---

[2] Indeed, respondents would argue that this constitutes the law of the case for all purposes.

CONCLUSION

Respondents Charlotte and Robert Kennedy respectfully request that writ of certiorari be denied.

Respectfully submitted,

MICHAEL M. ESSMYER
ESSMYER & TRITICO, L.L.P.
4300 Scotland
Houston, Texas 77007
(713) 868-1111

SUSAN A. ALLINGER
4300 Scotland
Houston, Texas 77007
(713) 868-1111

Counsel for Respondents

Supreme Court, U. S.
F I L E D
APR 12 1999
CLERK

No. 98-1424

In The

Supreme Court of the United States

October Term, 1998

COLLAGEN CORPORATION,

Petitioner,

v.

CHARLOTTE KENNEDY and ROBERT KENNEDY,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITIONER'S REPLY MEMORANDUM

FREDERICK DOUGLAS BAKER
Counsel of Record
KATHLEEN D. PATTERSON
SEDGWICK, DETERT, MORAN & ARNOLD
One Embarcadero Center, 16th Floor
San Francisco, California 94111-3628
Telephone: (415) 781-7900

Counsel for Petitioner

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

1809

TABLE OF CONTENTS

Page

PETITIONER'S REPLY MEMORANDUM 1

A. CERTIORARI SHOULD BE GRANTED TO DECIDE THE ISSUE OF INDEPENDENT VALIDATION 1

1. The Ninth Circuit's Opinion Is At Odds With *Daubert* On A Critical Issue That Divides The Circuits 1

2. The Issue Is Properly Before The Court .. 4

B. CERTIORARI SHOULD BE GRANTED TO DECIDE THE BURDEN OF PROOF ISSUE ... 5

C. CERTIORARI SHOULD BE GRANTED TO DECIDE WHETHER *DAUBERT* ESTABLISHES A STANDARD OF CERTAINTY FOR EXPERT CAUSATION TESTIMONY THAT SUPERSEDES SUBSTANTIVE STATE LAW 5

CONCLUSION 6

TABLE OF AUTHORITIES

Page

Federal Cases

Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378 (4th Cir. 1995) 3

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995) 2, 3, 4, 5

General Electric Co. v. Joiner, 522 U.S. 136, 118 S.Ct. 512 (1997) 3

In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717 (3d Cir. 1994), *cert. denied*, 513 U.S. 1190 (1995) 3

Kumho Tire Co. v. Carmichael, ___ U.S. ___, 1999 WL 153445, No. 97-1709 (March 23, 1999) 4

Mitchell v. Gencorp Inc., 165 F.3d 778 (10th Cir. 1999) 3

Moore v. Ashland Chemical, Inc., 151 F.3d 269 (5th Cir. 1998) (*en banc*) 3

Teague v. Lane, 489 U.S. 288 (1989) 6

Zuchowicz v. United States, 140 F.3d 381 (2d Cir. 1998) 3

PETITIONER'S REPLY MEMORANDUM

A. CERTIORARI SHOULD BE GRANTED TO DECIDE THE ISSUE OF INDEPENDENT VALIDATION

The Petition first presents this question: Does Rule 702 require the proponent of an expert opinion – an opinion that concededly (i) finds no support in the consensus view of either a majority or an acknowledged minority of experts in the field, (ii) finds no support in the published medical and scientific literature, and (iii) was not developed out of research but instead was formulated solely for litigation – to establish by independent validation that the methodology employed by the expert is scientifically reliable?

Kennedy does not contest the factual predicates. She in essence concedes that her hired-gun expert's opinion is no more than one man's belief, and that no other expert source – no text, no journal, no published study, no other expert witness – attests to the reliability of the expert's methodology.

Kennedy's brief in opposition attempts to persuade the Court not to review this issue for two substantive reasons. (Br. in Opp., pp. 3-5.) Neither has merit.

1. The Ninth Circuit's Opinion Is At Odds With *Daubert* On A Critical Issue That Divides The Circuits

Kennedy attempts to downplay the significance of the Ninth Circuit's error, and to ignore the conflict that

divides the circuits, in a discussion of "objective verification" and "independent validation" that is profoundly confused. (Br. in Opp., pp. 3-4.) Kennedy's confusion mirrors that of the Ninth Circuit – neither has drawn the necessary distinction between: (1) objectively verifiable facts or data, and (2) independent validation of the expert's methodology.

For example, as mentioned briefly in the Petition (p. 22), during the summer months there is a dramatic increase in watermelon consumption and in deaths by drowning. Suppose that a drowned man's heirs bring an action against a seller of watermelon; in response to a summary judgment motion, the heirs submit a physician's affidavit stating that he has studied the statistical data on summer drownings and watermelon consumption, he has examined the body and found that death was by drowning and the decedent consumed watermelon within 48 hours of death, and it is his opinion – to a reasonable degree of medical probability – that watermelon caused the drowning.

No doubt the statistics were accurate. So too the results of the examination. These facts and data are subject to objective verification. But could the heirs conceivably establish by **independent validation** that the physician's **methodology** – the formulation of a causation opinion based upon a spurious statistical association – is supported by the consensus view of other experts and the medical literature? Of course not.

In *Daubert II* (*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995)) the court said "the party proffering the evidence

must explain the expert's methodology and demonstrate in some **objectively verifiable** way that the expert has chosen a **reliable scientific method** and followed it faithfully." *Daubert II*, 43 F.3d at 1319 (emphasis supplied).

In *Kennedy* the court accepted the expert's opinion because he "relied upon a wide variety of objective, verifiable **evidence** in forming his opinion." (Pet. App., p. 5.) Following this statement, the court recites a litany of **data** the expert looked at. (Pet. App., p. 6.) What is utterly lacking – notwithstanding the court's pronouncement that the expert "used the traditional scientific methodology" (Pet. App., p. 6) – is **any** evidence that **any** expert in the field would look at the same data and reach the same conclusion.

There indisputably was not, in short, **any** independent validation – as *Daubert II* requires – for the expert's analytical leap from data to conclusion. See *General Electric Co. v. Joiner*, 522 U.S. 136, 118 S.Ct. 512, 519 (1997).

The split of authority on the question whether independent validation of an expert's **methodology** is required in a case such as this extends beyond the Ninth Circuit. The Fifth Circuit and the Tenth Circuit require such validation. *Moore v. Ashland Chemical, Inc.*, 151 F.3d 269 (5th Cir. 1998) (*en banc*); *Mitchell v. Gencorp Inc.*, 165 F.3d 778 (10th Cir. 1999). The Second Circuit, the Third Circuit, and the Fourth Circuit do not. *Zuchowicz v. United States*, 140 F.3d 381 (2d Cir. 1998); *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994), *cert. denied*, 513 U.S. 1190 (1995); *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378 (4th Cir. 1995).

The issue is of significant importance. The conflict among the circuits is irreconcilable absent the Court's review. Kennedy had made no reasoned argument to the contrary. The Court should grant certiorari and resolve the issue.[1]

2. The Issue Is Properly Before The Court

Respondent's suggestion that the issue of independent validation of an expert's methodology was not raised below (Br. in Opp., pp. 4-5) is fatuous. The issue was addressed by the district court (Pet. App., p. 18), was briefed in the court of appeals (Reply Mem. App., *infra*, pp. 2-10), and was addressed, albeit wrongly, by the court of appeals (Pet. App., pp. 5-11).

---

[1] Respondent raises the Court's recent decision in *Kumho Tire Co. v. Carmichael*, ___ U.S. ___, 1999 WL 153445, No. 97-1709 (March 23, 1999). (Br. in Opp., pp. 3-4.) Although *Kumho* does not directly address the issue raised by the Petition, it is significant here in one important respect. The district court here carefully reviewed the evidence, applied the principles of *Daubert I* and *Daubert II*, and concluded the expert's testimony was inadmissible. (Pet. App., pp. 14-21.) While the Ninth Circuit looked at the same evidence and drew a different conclusion, by no stretch of the imagination did the district court abuse its discretion under the standard established in *Kumho*: "[W]e conclude that **the trial judge must have considerable leeway** in deciding in a particular case how to go about determining whether particular expert testimony is reliable. . . . [W]hether *Daubert*'s specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge **broad latitude** to determine." *Kumho*, 1999 WL 152455 at *10, *11 (emphasis supplied).

B. CERTIORARI SHOULD BE GRANTED TO DECIDE THE BURDEN OF PROOF ISSUE

Collagen contends the proponent of expert testimony bears the burden of establishing, by a preponderance of the evidence, independent validation of the expert's **methodology**. This contention is supported by *Daubert II* and many federal district courts around the country. (See Pet., pp. 26-27 and cases there cited.)

It is undisputed there was no such evidence here. On that basis alone, under the prevailing view, the district court's ruling should have been affirmed. But it was not, the court of appeals stating that "Collagen has not introduced any evidence that Dr. Spindler's reasoning is not scientifically valid." (Pet. App., p. 10.)

By any reasoning, this is a 180-degree reversal of the burden of proof. Respondent's attempt to cast this as merely "an evidentiary issue" (Br. in Opp., p. 5) is unsupported by law or logic, and simply makes no sense.

C. CERTIORARI SHOULD BE GRANTED TO DECIDE WHETHER *DAUBERT* ESTABLISHES A STANDARD OF CERTAINTY FOR EXPERT CAUSATION TESTIMONY THAT SUPERSEDES SUBSTANTIVE STATE LAW

The Petition establishes that the Ninth Circuit ignored California's "more likely than not" requirement for an expert opinion on causation, substituting instead a vague "something less than a high degree of certainty" standard purportedly drawn from *Daubert*. (Pet., pp. 27-30.)

Kennedy's only response is to contend that because the Court denied certiorari in an earlier appeal where the Ninth Circuit made the same error, the Court "has no jurisdiction" to consider the issue, which is not "moot." This suggestion is, of course, shockingly misinformed:

> As we have often stated, the 'denial of a writ of certiorari imports no expression of opinion upon the merits of the case.' *United States v. Carver*, 262 U.S. 482, 490, 43 S.Ct. 181, 182, 67 L.Ed. 361 (1923) (Holmes). The 'variety of considerations [that] underlie denials of the writ,' *Maryland v. Baltimore Radio Show*, 338 U.S. 912, 917, 70 S.Ct. 252, 254, 94 L.Ed. 562 (1950) (opinion of Frankfurter, J.), counsels against according denials of certiorari any precedential value.

Teague v. Lane, 489 U.S. 288, 296 (1989) (additional citations omitted).

Kennedy does not dispute the substance of Collagen's Petition with respect to this issue. Her contention that the Court "has no jurisdiction" to consider the issue is facially preposterous.

CONCLUSION

The petition for writ of certiorari should be granted.

DATED: April 9, 1999

Respectfully submitted,

SEDGWICK, DETERT, MORAN & ARNOLD
FREDERICK D. BAKER

Attorneys for Petitioner
Collagen Corporation

App. 1

No. 97-16945

IN THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CHARLOTTE KENNEDY and ROBERT KENNEDY,

Plaintiffs and Appellants,

v.

COLLAGEN CORPORATION, et al.,

Defendants and Appellees.

On appeal from the United States District Court
for the Northern District of California
(No. CV-89-02331-CAL)

Honorable Charles A. Legge,
United States District Judge

APPELLEES' BRIEF

FREDERICK D. BAKER
KATHLEEN D. PATTERSON
KIRK C. JENKINS
SEDGWICK, DETERT, MORAN
& ARNOLD
One Embarcadero Center,
16th Floor
San Francisco, California 94111
Telephone: (415) 781-7900

Attorneys for Appellee
COLLAGEN CORPORATION

* * *

D. THE TESTIMONY OF SPINDLER IS NOT ADMISSIBLE UNDER DAUBERT, SO SUMMARY JUDGMENT WAS PROPERLY GRANTED

In order to be admissible under *Daubert*, Spindler's opinion that exposure to Zyderm caused Kennedy's injuries must meet two tests. First, Spindler's testimony must reflect "scientific knowledge," his findings must be "derived by the scientific method," and his work product

---

12/ (. . . continued)

F.3d 711, 716 (9th Cir. 1997), this Court decided that testimony about the modus operandi of criminals was "specialized knowledge" of law enforcement, not scientific knowledge. *United States v. Cordoba*, 104 F.3d 225, 230 (9th Cir. 1996) is identical. In *Thomas v. Newton International Enterprises*, 42 F.3d 1266, 1269-70 (9th Cir. 1994), this Court found that a longshoreman's testimony about whether a certain condition would be unusual on the docks and whether an experienced longshoreman would anticipate encountering a hazardous condition was "specialized knowledge." *McKendall v. Crown Control Corp.*, 122 F.3d at 807-08 involved the question of whether the testimony of an engineer who had investigated hundreds of forklift accidents that a certain safety device was feasible was "specialized" or "scientific" knowledge. In *United States v. Bighead*, 128 F.3d 1329, 1330 (9th Cir. 1997), this Court found that an expert's testimony about the characteristics she had observed in the more than thirteen hundred alleged victims of childhood sexual abuse she had interviewed was "specialized" knowledge. *Tyrus v. Urban Search Management*, 102 F.3d 256, 263 (7th Cir. 1996) holds that *Daubert* is applicable to a social science expert, but that the "measure of intellectual rigor" required of a particular witness will depend in part upon her field of expertise.

must amount to "good science." *Daubert I*, 509 U.S. at 589-90, 593-94; *Daubert II*, 43 F.3d at 1315. Second, Spindler's testimony must be " 'relevant to the task at hand,' " i.e., it must logically advance a material aspect of Kennedy's case. *Daubert I*, 509 U.S. at 591; *Daubert II*, 43 F.3d at 1315. The district court ruled that Spindler's testimony was inadmissible pursuant to the first prong of the *Daubert* test, and therefore never reached the second issue. In fact, Spindler's testimony meets neither prong of the *Daubert* test.

1. Spindler's Testimony is Not Scientific Knowledge Derived By the Scientific Method, and Therefore Fails the First Prong of the Daubert Test

a. The *Daubert* Factors

In *Daubert I*, the Supreme Court discussed several factors which a federal court could consider in determining whether a proposed expert's testimony was "good science" derived by the "scientific method." "[A] key question to be answered," the Court observed, is "whether [the theory] can be (and has been) tested." A court should consider the known or potential rate of error in the hypothesis. The court may properly consider whether a theory is generally accepted in the scientific community, and a theory which has attracted " 'only minimal support' . . . may properly be viewed with skepticism." Finally, a court may consider whether or not the theory has been subjected to peer review and publication. *Daubert I*, 509 U.S. at 593-94.

On remand in *Daubert*, this Court noted that a "very significant fact" in determining whether an expert's testimony was "good science" was whether or not his proposed testimony grows naturally and directly out of research he has conducted independent of the litigation, or whether he has developed his opinions expressly for the purpose of testifying. *Daubert II*, 43 F.3d at 1317. If the expert *has* developed his opinions solely for his testimony, then the proponent of the evidence "must come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.' " *Id.* at 1317-1318.

b. Spindler's Causation Theory Was Developed Expressly For the Purpose of Testifying, and Has Not Been Peer Reviewed or Published

Kennedy claims that Spindler's theory has been published. *See* "Association Between Bovine Collagen Dermal Implants and a Dermatomyositis or a Polymyositis-Like Syndrome," *Annals of Internal Medicine*, Vol. 118, No. 12 (June 15, 1993). (Appellants' Ex., Tab C, Exh. B thereto.) But as the district court recognized, that article offers no support to Spindler's theory that exposure to Zyderm can cause SLE or "atypical SLE."

Spindler's article purports to describe nine patients who developed "dermatomyositis ["DM"] or polymyositis-like ["PM"] syndrome" after exposure to Zyderm or Zyplast (another product manufactured by Collagen). According to the authors, the conditions (DM/PM) are autoimmune disorders which they describe as

"uncommon . . . myopathologic abnormalities. . . . " (*Id.* at p. 920.) There is no evidence in this case, however, that Kennedy has either dermatomyositis or polymyositis. All available evidence, provided by Kennedy's own experts, establishes that she does not. (Dkt. 198, Exh. O, 48:5-11; Exh. P, 17:11-26; 18:1-4; Appellees' Ex., 153, 159-60.).

Cross-examined about his article, and its relevance to *this* case, Spindler admitted that:

(1) the article was confined to a patient population that had DM/PM, *not* SLE (Dkt. 198, Exh. N, 76:25-77:7; Appellees' Ex., 138-39);

(2) Kennedy did *not* have a delayed hypersensitivity response to collagen (as had eight of the nine DM/PM patients) (Dkt. 198, Exh. N, 77:13-20; Appellees' Ex., 139);

(3) Kennedy did *not* have human Leukocyte Antigens (HLA) as did the DM/PM patients. (Dkt. 198, Exh. N, 79:13-80:12; Appellees' Ex., 141-42); and

(4) Kennedy did *not* have proximal muscle weakness, as did the DM/PM patients. (Dkt. 198, Exh. N, 80:13-24; Appellees' Ex., 142.)

Spindler conceded: "We're talking here [in the case of Kennedy] about a *different* autoimmune disorder," *one which was not the subject of the study.* (Dkt. 198, Exh. N, 80:13-24; 81:1-6; Appellees' Ex., 142-43.)

Spindler's article does not support his claim that Zyderm can cause SLE or "atypical SLE." Kennedy is the only patient he has ever examined who was both exposed to Zyderm and claimed to have either disorder. (Dkt. 198, Exh. N, 75:14-18; Appellees' Ex., 137.) Since Spindler's

theory has not been subjected to peer review and publication, Kennedy must produce "objective, verifiable evidence" that Spindler's opinion is based upon " 'scientifically valid principles.' " Otherwise, Spindler's testimony is inadmissible.

c. Kennedy's Own Experts Admit That Spindler's Theory Has Not Been, and Cannot Be, Tested

According to Spindler, Kennedy has "atypical SLE." His diagnosis is based on the fact that her constellation of signs and symptoms do not meet the minimum criteria for the diagnosis of true SLE. (Dkt. 193, Exh. L, 18:7-25, 19:1; Appellees' Ex., 104-05.) Both he and plaintiffs' expert Dr. Masi say that "atypical SLE" is recognized as a disease entity within the rheumatology community, but neither offers any foundation or explanation for that opinion. (Appellants' Ex., Tab D, Exh. 1, ¶ 5.) In fact, both Spindler and Masi admit that neither the American College of Rhuematology or anyone else has a standard or accepted criteria for what constitutes "atypical SLE." (Appellants' Ex., Tab D, Exh. 1, ¶ 4.)

Apparently, then, "atypical SLE" is an umbrella term for any lupus-like autoimmune disease which a physician cannot diagnose. Spindler admits there is no "signature disorder" to suggest that the cause of "atypical SLE" is collagen exposure or even that the cause is the same for all women with similar signs and symptoms. (Dkt. 198, Exh. N, 162:20-25, 163:1-25; 164:1-6; Appellees' Ex., 145-47.)

Given the vagueness of the term "atypical SLE," it is hardly surprising that not one epidemiological or animal study has ever shown that Zyderm causes SLE or "atypical SLE." (Dkt. 193, Exh. L. 61:5-62:12, 65:12-20; Appellees' Ex., 111-13.) In fact, both Spindler and Dr. Masi admit that without standard criteria for diagnosis, no epidemiological study *can* be done, because it would be impossible to compare the number of cases of "atypical SLE" in the zyderm-exposed population with the number of expected cases of "atypical SLE" in the non-exposed population. (Appellants' Brief at 21; *see* Appellants' Ex., Tab D, Exh. 1, ¶ 4.) Obviously, the lack of any consensus as to exactly what constitutes "atypical SLE" would introduce an enormous rate of error into any such study.

The court disposed of similar claims that "atypical" autoimmune diseases are caused by silicone breast implants in *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387 (D.Or. 1996). Granting defendants' motion to exclude any expert testimony on medical causation, the court found it significant that:

> (1) criteria for "atypical connective tissue disease" ("ACTD"), although proposed, had not been tested;
>
> (2) there was no "signature disorder" to suggest the cause of ACTD was silicone exposure or that the cause of the signs and symptoms of ACTD was the same for all women; and
>
> (3) plaintiffs' hypothesis that silicone breast implants caused ACTD had not been tested epidemiologically.

Id. at 1402.

On the basis of these facts, conceded by plaintiffs' experts as they are conceded here, the court concluded:

> *Because ACTD is at best an untested hypothesis, there is no scientific basis for any expert testimony as to its causes and presence in plaintiffs.* Therefore, defendants' motions are granted as regards any expert testimony relating to the existence and causation of any atypical, silicone-caused auto-immune disorder.

Id. (emphasis supplied).

Spindler's theory that Zyderm causes "atypical SLE" is, like plaintiffs' theory of silicone-caused ACTD in *Hall*, an untested hypothesis based upon the only patient Spindler has ever examined with both Zyderm exposure and "atypical SLE": Kennedy. "Case reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls." *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. at 1411, citing *Casey v. Ohio Medical Products, supra*, 877 F.Supp. 1380; *Muzzey v. Kerr-McGee Chemical Corp.*, 921 F.Supp. 511, 519-20 (N.D. Ill. 1996); *In re Three Mile Island Litigation Cases Consolidated II*, 911 F.Supp. 775, 795-96 (M.D. Penn. 1996); *Grimes v. Hoffman-LaRoche, Inc.*, 907 F.Supp. 33, 35 n.2 (D.N.H. 1995). Therefore, an analysis of case reports "cannot be the basis of an opinion based on scientific knowledge under *Daubert*." *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. at 1411.

Spindler is being offered to testify to a hypothesis which, by his own admission, has not been and cannot be tested. The district court correctly found that Spindler's hypothesis that Zyderm causes "atypical SLE" is unreliable, inadmissible and insufficient to create a triable issue

of fact in regard to causation. *See Hall v. Baxter Healthcare Corp.*, 947 F.Supp. at 1406.

d. ~Spindler's Theory Has Attracted No Support in the Scientific Community

Finally, Spindler's theory that Zyderm causes SLE or "atypical SLE" has attracted no support whatsoever in the scientific community. As noted above, no epidemiological or animal study has ever found any association between Zyderm and SLE or "atypical SLE." There is no consensus in the rheumatologic community that Zyderm causes SLE. (Dkt. 193, Exh. L, 60:9-17; Appellees' Ex., 110.) Nor was Spindler able to point to any textbooks which say that Zyderm causes SLE or "atypical SLE." (Dkt. 193, Exh. L. 67:11-14; Appellees' Ex., 115.)

The district court correctly found that *none* of the various factors discussed in *Daubert I* and *Daubert II* weigh in favor of a finding that Spindler's testimony is based on "scientifically valid principles." Spindler's testimony was properly excluded, and summary judgment should be affirmed.

* * *

proposition, *Moore v. Ashland Chemical*, has been vacated for *en banc* review by the Fifth Circuit.

Spindler's opinion is untested and untestable speculation with no basis in the scientific method. The district court correctly found that *none* of the *Daubert* factors weigh in favor of a finding that Spindler's methodology is reliable. But even if that decision were erroneous, Spindler does not give his causation opinion to the level

of certainty required by California law, so Spindler's testimony is inadmissible under the "fit" prong of the *Daubert* test as well.

The judgment should be affirmed in all respects.

Dated: February 6, 1998.

Respectfully submitted,

SEDGWICK, DETERT, MORAN & ARNOLD

By /s/ Frederick D. Baker
Frederick D. Baker

Attorneys for Appellee
COLLAGEN CORPORATION